IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-230 (GMS)
	)	
APOTEX, INC.	)	**JURY TRIAL DEMANDED**
	)	
Defendant.	)	

APOTEX'S ANSWERING BRIEF IN OPPOSITION TO MERCK'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

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The background set forth in Plaintiff Merck & Co., Inc.'s ("Plaintiff's" or "Merck's") motion is essentially correct with some omissions. Merck sued Defendant Apotex, Inc. ("Defendant" or "Apotex") for patent infringement based upon Apotex's filing of an Abbreviated New Drug Application ("ANDA") for the generic drug alendronate sodium, which Merck sells under the trademark FOSAMAX®. (D.I. 1) Apotex answered and counterclaimed for a declaratory judgment that Merck's patents were invalid and/or not infringed. (D.I. 8) Merck filed its answer to Apotex's counterclaim on May 30, 2006. (D.I. 11) In its paragraph IV letter to Merck, Apotex offered to provide confidential access to certain information in its ANDA for the purpose of determining whether Merck could bring an infringement action. Merck did not take advantage of the offer. Shortly after it sued Apotex, Merck informally requested excerpts from Apotex's ANDA. After reviewing the excerpts from Apotex's ANDA, Merck provided a covenant not to sue Apotex on August 7, 2006. Merck subsequently filed a motion to dismiss for lack of subject matter jurisdiction in light of the covenant. (D.I. 15)

SUMMARY OF ARGUMENT

1. This case is not moot because of the adverse consequences a dismissal without a finding of invalidity and/or noninfringement has on Apotex's ability to enter the market with a generic version of Merck's Fosamax drug. Cases under the Hatch-Waxman scheme are different from traditional patent infringement cases. An actual controversy remains over whether Merck's patents are invalid and/or noninfringed despite Merck's presentation to Apotex of a covenant not to sue. Without a court decision finding Merck's patents invalid and/or not infringed, Apotex is denied its right to

compete with Merck for want of a "triggering event" and will be injured by delayed entry into the market. The collateral legal consequence of a dismissal without the necessary triggering "court decision" constitutes an exception to the mootness that Merck claims to have created with its covenant not to sue. Thus, this case is not moot and this Court has subject matter jurisdiction.

2. Furthermore, this Court should decline to dismiss this case because Merck is manipulating this Court's jurisdiction to avoid the adverse judgment it would inevitably receive if this case went forward. If this case is dismissed without a decision Merck will not have to compete against Apotex and other potential generic manufacturers, with the exception of the first generic manufacturer to file an ANDA during the first 180 days of generic competition. When Merck is competing against only one generic competitor the price Merck can charge for its brand name drug remains higher than it would be if several generics enter the market. By filing a patent infringement suit but then presenting a covenant not to sue and attempting to dismiss Apotex's counterclaims for lack of subject matter jurisdiction, Merck is manipulating the Court's jurisdiction to its benefit and to the detriment of Apotex and the other subsequent generics who are delayed from entering the market. The Supreme Court has allowed courts to retain jurisdiction to avoid such manipulation.

3. This Court also has subject matter jurisdiction because there is an actual case or controversy under the Supreme Court's test for determining case or controversy under Article III of the Constitution. The three-part test for a justiciable controversy is easily satisfied in this case. First, Apotex is injured because without a court decision finding the patents invalid or not infringed, Apotex suffers delay in bringing its product

to market. Second, this injury is directly traceable to Merck's conduct—Merck filed suit, then presented Apotex with a covenant not to sue, and sought dismissal of Apotex's counterclaims as moot. Third, a favorable (and prompt) decision will redress Apotex's injury because if it prevails, Apotex and all other generics who have filed an ANDA for alendronate sodium will be able to enter the market on February 6, 2008.[1] Otherwise, all the generic manufacturers are prohibited from entering the market until 180 days after the first generic filer (in this case, Teva Pharmaceuticals USA, Inc. ("Teva")) enters the market.

4. The Court should therefore find that it has subject matter jurisdiction over Merck's claims and Apotex's counterclaims and should use its discretion to exercise jurisdiction. A resolution in Apotex's favor will not only prevent injury to Apotex but will also benefit consumers by making generic versions of Merck's Fosamax available sooner and at a lower price.

STATEMENT OF FACTS

Merck is the owner of a number of patents listed for a drug sold by Merck under the trademark Fosamax. Launched in 1995, Fosamax is used for treatment and prevention of osteoporosis. Fosamax was Merck's second largest selling drug in 2005, with nearly $3.2 billion in sales worldwide.[2] Thus, Fosamax is a vitally important component in

[1] Assuming the court's decision is final and unappealable no later than August 6, 2007.

[2] *See* Merck's 2005 Annual Report at p. 23, (http://www.merck.com/finance/annualreport/ar2005/pdf/Merck_2005_Financial_Review.pdf). The Court may consider matters outside the pleadings in determining whether subject matter jurisdiction exists. *See Martek Biosciences Corp. v. Nutrinova, Inc.*, 2004 WL 2297870, at *3 (D. Del. Oct. 8, 2004) (Ex. A hereto); *Medtronic Ave, Inc. v. Boston Scientific Corp*, 2004 WL 769365, at *2-3 (D. Del. Apr. 5, 2004) (Ex. B hereto).

Merck's drug portfolio and Merck is undoubtedly interested in maintaining its market share and profits for as long as it can.[3]

Currently, Merck's market share is protected by its patents covering Fosamax that are listed in the Orange Book. The active ingredient in Fosamax is alendronate sodium. Merck's patent on this active ingredient is U.S. Pat. No. 4,621,077 ("the '077 patent"). The '077 patent is set to expire on August 6, 2007, but Merck has an additional FDA exclusivity until February 6, 2008. Thus, no generic maker can receive final FDA approval for alendronate sodium prior to February 6, 2008.[4] Merck also has a number of other patents that it is using to extend its monopoly of alendronate sodium. These patents relate, however, to various formulations of the active ingredient and to dosage strategies.[5]

Apotex filed an ANDA pursuant to the Hatch-Waxman Act seeking approval for a generic version of alendronate sodium. On February 24, 2006, Apotex sent a "paragraph IV" letter to Merck, notifying Merck that it had filed an ANDA for alendronate sodium and that, other than the '077 patent, the patents listed by Merck in the Orange Book for

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[3] Generic drugs can have a dramatic effect on the profits of the pioneer or brand name drug producer. In one case, for example, Abbott Laboratories predicted that it would lose 40% of its sales of a prescription drug that it had developed and patented, within one month of generic entry, 64% percent within two months, and 78% after eleven months. *See Abbott Laboratories v. Andrx Pharmaceuticals, Inc.*, 2005 WL 1323435, at *15 (N.D.Ill. June 3, 2005) (Ex. C hereto), *vacated on other grounds*, 452 F.3d 1331 (Fed. Cir. 2006).

[4] Merck sued Teva, presumably the first ANDA applicant for alendronate sodium, for infringement of the '077 patent, and Merck's '077 patent was found valid and infringed by Teva's ANDA. *See Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 228 F.Supp.2d 480 (D. Del. 2002), *aff'd*, 347 F.3d 1367 (Fed. Cir. 2003).

[5] The patents directed to the alendronate formulations that Merck asserted in its complaint are: US. Patent Nos. 5,358,941 ("the '941 patent"), 5,681,590 ("the '590' patent"), 5,894,726 ("the '726 patent"), 6,008,207 ("the '207 patent"), 6,090,410 ("the '410 patent") and 6,194,004 ("the '004 patent"). The patents directed to the dosage regimens asserted in the complaint are: U.S. Patent Nos. 5,994,329 ("the '329 patent"), 6,015,801 ("the '801 patent"), and 6,225,294 ("the '294 patent").

alendronate sodium, *i.e.*, the nine patents that are at issue in this case, were either invalid, unenforceable, and/or not infringed.[6] *See* 21 U.S.C. §355(j)(2)(B)(iv). Apotex offered in its paragraph IV letter to provide Merck with certain confidential information. *See* 21 U.S.C. §355(j)(5)(C).

Under the Hatch-Waxman Act, Apotex's paragraph IV letter was an act of infringement. *See* 35 U.S.C. § 271(e)(2)(A). Without requesting to see Apotex's confidential information, Merck filed suit on April 7, 2006. Apotex subsequently provided Merck with certain confidential information from its ANDA in order to resolve this matter. That information showed that Apotex does not use a formulation that is covered by Merck's formulation patents. Further, two claims of Merck's '329 patent covering the once-weekly dosage of alendronate sodium had been held invalid prior to Merck's filing suit. *See Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 1388, *cert. denied*, 126 S.Ct. 488 (2005). For similar reasons, Merck's other dosage patent is invalid. Thus, Apotex contends that Merck's nine patents asserted in this action are either invalid or will not be infringed by Apotex's ANDA for alendronate sodium.

After Apotex provided its confidential information to Merck, Merck indicated that it would present Apotex with a covenant not to sue. Merck refused to agree to any dismissal order in which the Court made any findings that Apotex either did not infringe Merck's patents or that Merck's patents were invalid.

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[6] Apotex made a paragraph III certification in its ANDA with respect to the '077 patent certifying that it would not market its generic version until the expiration of the '077 patent and its pediatric exclusivity, which were set to expire on February 6, 2008.

A decision by the court finding that all of Merck's listed patents are either not infringed or invalid would trigger the 180-day exclusivity period that is normally available to the first generic to file an ANDA, whether it has marketed the product or not. The 180-day exclusivity period is triggered by the earlier of (1) the first generic's entry into the market; or (2) a decision by the court finding that the patent or patents listed in the Orange Book are either invalid or not infringed. *See* 21 U.S.C. §355(j)(5)(B)(iv). Thus, as it stands now, neither Apotex, nor any other subsequent generic, may enter the market until Teva markets a generic version.

Merck does not want to trigger the 180-day exclusivity period because it wants to compete with at most one generic rather than several generics when the exclusivity for its '077 patent expires. If there is a triggering event at least 180 days prior to February 6, 2008 (i.e. by at least August 6, 2007), then all the subsequent generic filers can market their generic drugs at the same time on February 6, 2008 and Merck would then have to compete with a number of generics rather than just one.[7] Recent history has shown that brand name drug companies will compete with the first generic by offering their own generic product. Prices in a two-generic market are higher than in a multi-generic market. Merck stands to lose even more of its market share, and drug prices will be lower, if there are more competitors than if there is only one. Thus, Merck wants to control the market by avoiding a "triggering event."

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[7] The FDA does not make public the number or identities of entities that have filed ANDAs for a particular drug. Apotex understands, however, that a number of generic manufacturers have filed ANDAs for alendronate sodium, including Watson Laboratories, with whom this Court is familiar. *See Merck & Co., Inc. v. Watson Laboratories, Inc.*, 2006 WL 1537375 (D. Del. June 2, 2006) (Ex. D hereto).

Consequently, brand name drug companies, like Merck in this case, have adopted a number of strategies to avoid triggering the 180-day exclusivity period. In some cases, the brand name drug company has settled its lawsuit with the first generic filer and then declined to sue the subsequent generic filers. If the settlement agreement includes an agreement by the first generic not to market or to delay its entry into the market, then there is no "court decision" or "market entry" that triggers the first generic applicant's 180-day exclusivity period. This creates a bottleneck that prevents any subsequent generic manufacturer from getting FDA approval until the first generic enters the market and after the 180 days runs, or until the relevant listed patents expire, or until a subsequent generic applicant can itself trigger the running of the 180-day period. When subsequent generic filers attempt to bring a declaratory judgment action seeking a declaration of invalidity, unenforceability or noninfringement in order to create the "court decision" triggering event, the brand name drug companies seek a dismissal for lack of subject matter jurisdiction.[8] The bottleneck thus created benefits the brand name drug company because it can maintain its market share and price without generic competition.

The agreements between the brand name drug company and the first generic applicant to delay the first applicant's entry into the market in order to delay entry by

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[8] This pattern has occurred in a number of cases. *See, e.g.*, *Teva Pharmaceuticals, USA, Inc. v. United States Food & Drug Administration*, 398 F. Supp. 2d 176 (D.D.C. 2005), vacated and remanded, 441 F.3d 1 (D.C.Cir. 2006); *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187 (S.D.N.Y. 2005), *aff'd*, 159 Fed.Appx. 1013 (Fed. Cir. 2005), petition for cert. filed, 74 U.S.L.W. 3476 (U.S. Feb. 9, 2006); *Glaxo Group Ltd. v. Dr. Reddy's Labs, Ltd*, 325 F. Supp. 2d 502 (D.N.J. 2004); *Mutual Pharmaceuticals Co, Inc. v. Pfizer, Inc.*, 307 F. Supp. 2d 88 (D.D.C. 2004); *Eon Labs, Inc. v. Pfizer Inc.*, 2005 WL 1705295 (S.D.N.Y. July 19, 2005) (Ex. E hereto); *Mylan Pharmaceuticals Inc. v. Merck & Co, Inc.*, 2005 WL 2850137 (M.D.Pa. Oct. 28, 2005) (Ex. F hereto); *Dr. Reddy's Labs, Ltd. v. Pfizer Inc*, 2003 WL 21638254 (D.N.J. July 8, 2003) (Ex. G hereto); *Torpharm, Inc. v. Pfizer Inc*, 2004 WL 1465756 (D. Del. June 28, 2004) (Ex. H hereto), vacated and remanded sub nom. *Apotex Inc. v. Pfizer Inc.*, 125 Fed.Appx. 987 (Fed. Cir. 2005).

subsequent generic manufacturers due to this bottleneck have raised a number of concerns due to their anticompetitive effect and harm to consumers. *See, e.g.*, Prepared Statement Of The Federal Trade Commission Before the Special Committee On Aging of the United States Senate on Barriers to Generic Entry, July 20, 2006, at pp. 20-24 (Ex. I hereto).

This case involves a variation of that strategy. Instead of not bringing suit at all, Merck files suit but then after being presented with evidence that the generic does not infringe, Merck presents the generic with a covenant not to sue. Merck then seeks to dismiss the case as moot. With no finding of nonfringement or invalidity from the court, Merck prevents a triggering event from occurring. This was the situation in *Merck & Co. Inc. v. Watson Laboratories, Inc.*, 2006 WL 1537375 (D. Del. June 2, 2006) and the pattern repeats here. By manipulating the Court's jurisdiction in this way, Merck is able to keep all subsequent generic filers out of the market during the first 180 days after the first generic filer enters. If Merck has an agreement with the first generic applicant (*i.e.*, Teva) to delay its entry into the market beyond February 6, 2008, subsequent generic filers, like Apotex, will be prevented from entering the market by this bottleneck until the listed patents expire. Even if there is no agreement with the first generic manufacturer, Merck's strategy of presenting covenants not to sue to subsequent generic manufacturers that it knows will not infringe any valid patent it owns will keep those subsequent generic companies out of the market for the first 180 days, effectively limiting the market to the first generic filer and Merck's own generic version, if it decides to make one.[9]

[9] Apotex is currently researching the anticompetitive nature of Merck's actions and will seek leave to amend its counterclaim to bring these additional claims, including an antitrust violation, if warranted.

ARGUMENT

I. THE COLLATERAL CONSEQUENCES DOCTRINE PRECLUDES MOOTNESS AND PROHIBITS MERCK FROM MANIPULATING THIS COURT'S JURISDICTION TO AVOID AN ADVERSE JUDGMENT

A. Under The Collateral Consequences Doctrine This Case Is Not Moot

Merck contends that the covenant not to sue moots Apotex's counterclaim. The burden of establishing mootness rests with the party raising the issue. *See NEC Corp. v. United States*, 151 F.3d 1361, 1369 (Fed. Cir. 1998). The burden of demonstrating mootness "is a heavy one." *County of Los Angeles v. Davis*, 440 U.S. 625, 631, 99 S.Ct. 1379, 1383 (1979); *Surrick v. Killion*, 449 F.3d 520, 526 (3d Cir. 2006). There is no question that Apotex had standing to assert its counterclaim when it did and that this was a live case or controversy at that time. It is only due to an intervening event, *i.e.*, Merck's covenant not to sue, that Merck contends this case is moot. Thus, Merck bears the "heavy" burden of establishing mootness. *See also Friends Of The Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 190, 120 S.Ct. 693, 709 (2000) ("there are circumstances in which the prospect that a defendant will engage in (or resume) harmful conduct may be too speculative to support standing, but not too speculative to overcome mootness").

If this were an ordinary patent infringement case, then Merck's covenant not to sue would likely moot this case. *See Spetronics Corp. v. H.B. Fuller Company, Inc.*, 940 F.2d 631, 638 (Fed. Cir. 1991); *Super Sack v. Chase*, 57 F.3d 1054, 1059 (Fed. Cir. 1995). But this is a Hatch-Waxman case where dismissing this case as moot without findings has the collateral consequence of depriving Apotex of a triggering event that would allow it to enter the market at the same time as the first generic filer. Under the

collateral consequences exception to mootness, a case or controversy remains to satisfy subject matter jurisdiction.

The fact that there are collateral consequences creates an exception to mootness. Even where an intervening event "may moot a claim in terms of the court's inability to undo or grant effective relief as to past acts or conditions, if those past acts have present, future, or collateral consequences then judicial review may nevertheless remain available." 15 Moore's Federal Practice, §101.99[3]; *see also Spencer v. Kemna*, 523 U.S. 1, 7-8, 118 S.Ct. 978, 983 (1998). For example, in the criminal context, the release of a prisoner will not necessarily moot a challenge to the propriety or legality of the conviction if there are continuing collateral consequences such as the deprivation of the right to vote, to hold office, or to engage in certain businesses. *Id.*

In the present case, dismissing Apotex's counterclaim for lack of subject matter jurisdiction based on mootness has the collateral consequence of denying Apotex a court finding on invalidity or noninfringement that would trigger the first generic applicant's 180-day period of exclusivity. Apotex's entry into the market will be delayed until the first generic manufacturer enters the market, and then another 180 days thereafter.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (hereinafter "MMA"), explicitly allows subsequent generic drug makers to bring a declaratory judgment action if the generic manufacturer is not sued by the patent holder within 45 days from notifying the patent holder of its paragraph IV certification in its ANDA. *See* 21 U.S.C. §355(j)(5)(C) (Supp. 2004). The MMA also provides that: "courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought...under section

2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. §271(e)(5) (Supp. 2004). The intent of the MMA was to provide a way for a subsequent generic drug maker who had not been sued to obtain a court decision, thus triggering the 180-day exclusivity period of the first generic filer and relieving the bottleneck that keeps subsequent generic filers from entering the market.

The Federal Circuit has held that a generic drug manufacturer's right to the 180-day exclusivity period is a collateral consequence that rendered a case not moot. In *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1345 (Fed. Cir. 2003), the Federal Circuit held that certain of Apotex's claim were not moot "because Apotex's rights to the statutory 180-day period of market exclusivity may be affected by a decision on those issues in this appeal." The issue in *Thompson* was whether there could be multiple 30-month stays of approval resulting from additional patents listed in the Orange Book after an ANDA is filed. While the case was on appeal, the FDA took the position that the Hatch-Waxman Act allowed only one 30-month stay for each ANDA and accordingly granted final approval of Apotex's ANDA. *Id.* at 1341. However, the FDA ruled that Apotex would have to share in the 180-day period of market exclusivity because it was not the first to file paragraph IV certifications for all of the listed patents. *Id.* at 1341-42.

SmithKline and the FDA argued that the appeal was moot because there were no more 30-month stays and Apotex's ANDA had been approved. *Id.* at 1344-45. Apotex argued that the appeal was not moot because the improper listing of patents in the Orange Book had a continuing prejudicial impact on Apotex's interests, specifically that Apotex's 180-day period of exclusivity remained in jeopardy of being triggered by a court decision based on one or more of the patents. *Id.* at 1345. The Federal Circuit held

that Apotex's claims, including its claim for de-listing of improperly listed patents, were not moot because the outcome of Apotex's claims might affect Apotex's rights to the statutory 180-day period of market exclusivity. *Id.* at 1345.

The decision in *Apotex, Inc. v Thompson* compels a finding that this case is not moot. Although Apotex received all the relief it originally sought in the *Thompson* case, *i.e.*, approval of its ANDA, it still had an interest in determining a number of other issues because of the collateral consequences those issues had on its 180-day market exclusivity. Similarly, in the present case, Merck's covenant not to sue does not resolve the collateral issue of Apotex's interest in a triggering event that would trigger the first generic applicant's 180-day market exclusivity, and allow Apotex to enter the market without waiting until the first generic applicant entered the market.

B. The Court Should Not Allow Merck To Manipulate Jurisdiction To Avoid An Adverse Judgment

Moreover, Merck's strategy of seeking dismissal by presenting Apotex with a covenant not to sue is an attempt to manipulate the jurisdiction of this Court in order to avoid not only an adverse judgment but also one that would trigger the first generic applicant's 180-day market exclusivity and allow Apotex, as well as possibly several others, to enter the market on February 6, 2008.

The Federal Circuit agreed that the district court was correct in not allowing its jurisdiction to be manipulated in this way in *Minnesota Mining and Manufacturing Co. v Barr Laboratories, Inc.*, 289 F.3d 775 (Fed. Cir. 2002). In that case, 3M was seeking dismissal of its patent claims without prejudice pursuant to Fed. R. Civ. P. 41(a)(2). At that time, 3M apparently thought that a dismissal without prejudice would not have triggered the first ANDA applicant's 180-day market exclusivity period, but a dismissal

with prejudice would have.[10] The district court held that 3M was not entitled to a voluntary dismissal simply to escape an adverse judgment. *Id.* at 779; *see also Minnesota Mining and Manufacturing Co. v. Barr Laboratories, Inc.*, 139 F. Supp. 2d 1109, 1116 (D. Minn. 2001), *aff'd*, 289 F.3d 775 (Fed. Cir. 2002).

The Federal Circuit held that the district court did not abuse its discretion in denying 3M's motion for a dismissal without prejudice. In doing so, the Federal Circuit implicitly recognized the collateral consequence that a dismissal without prejudice might have on the 180-day exclusivity trigger. *Id.* at 780. Without resolving whether the form of the dismissal would or would not have consequences in the FDA proceedings, the court held that the parties' dispute over the form of the dismissal was enough to create a controversy for subject matter jurisdiction. *Id.* Indeed, the court noted that "under the circumstances, a dismissal without prejudice might well have constituted an abuse of discretion since 3M was plainly seeking to avoid an adverse judgment." *Id.* at 784. Thus, a court's interest in preventing a party from manipulating jurisdiction to achieve a particular result may be grounds to find a case is not moot. *See also City of Erie v. Pap's A.M.*, 529 U.S. 277, 288, 120 S.Ct. 1382 (2000) (nude dancing club's voluntary cessation of business after state court found city's ordinance unconstitutional did not moot case since city was suffering on-going harm from adverse decision and nude dancing club was attempting to manipulate jurisdiction to insulate favorable decision from further review).

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[10] In *Teva Pharmaceuticals, USA, Inc. v. United States Food & Drug Administration*, 182 F.3d 1003, 1009 (D.C. Cir. 1999), the Federal Circuit held that the FDA's failure to find that the district court's dismissal of the ANDA applicant's declaratory judgment complaint against the patent holder was a "court decision" that triggered the first ANDA applicant's 180-day exclusivity period was "arbitrary and capricious."

Similarly, in the present case, Merck and Apotex both have legally cognizable interests in the outcome of this case. Merck wants to avoid an adverse decision in terms of a judgment of invalidity or noninfringement because such a decision would constitute a triggering event and Merck would have several generic manufacturers to compete against instead of one during the first 180 days after February 6, 2008. Apotex, on the other hand, can trigger the first generic applicant's period of market exclusivity if the Court finds that Merck's patents are invalid or not infringed by Apotex's generic version, and thus be able to market at the same time as the first generic applicant if the triggering event occurs at least 180 days prior to February 6, 2008.

This is not a case where Apotex brought a declaratory judgment action after not being sued by the brand name drug company. Rather, Merck filed suit first seeking this Court's intervention. It was only after Merck received information from Apotex and concluded that Apotex either did not infringe or that its patents were invalid that Merck now seeks to revoke this Court's jurisdiction by providing the covenant not to sue and voluntarily dismissing this case. As in 3M and *City of Erie*, this Court should not allow its jurisdiction to be manipulated in such a manner. There is an ongoing controversy here, otherwise Merck would have agreed to a dismissal in a form that would have included a finding of invalidity and/or noninfringement by the Court. Merck has steadfastly refused to agree to any such order to avoid triggering the first generic applicant's 180-day exclusivity so it could protect its market share for as long as possible.

II. ARTICLE III'S CASE OR CONTROVERSY REQUIREMENT IS SATISFIED

This Court has jurisdiction because there is an actual controversy here. In order for this Court to have subject matter jurisdiction under the Declaratory Judgment Act,

there must be "a case of actual controversy." 28 U.S.C. §2201(a). This "actual controversy" requirement in the Declaratory Judgment Act parallels the "case or controversy" requirement of Article III of the Constitution. *See EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996). An "actual controversy" under Article III requires (1) an actual or imminent injury-in-fact, (2) that is fairly traceable to the defendant, and (3) is redressible by a favorable decision. *See Bennett v. Spear*, 520 U.S. 154, 167, 117 S.Ct. 1154 (1997); *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40, 57 S.Ct. 461 (1937).

All three criteria are met in this case. Apotex has filed an ANDA to market a generic version of alendronate sodium that will not infringe any valid patents held by Merck. Apotex needs a decision from this Court, however, finding that Merck's patents are invalid or not infringed in order to constitute a "triggering event" of the first generic applicant's 180-day period of exclusivity. If this case is dismissed without such a finding, Apotex will not be able to compete with Merck at the same time as the first generic manufacturer enters the market, and if there is an agreement between Merck and the first generic manufacturer to delay the first generic's entry beyond February 6, 2008, then Apotex's entry into the market will be further delayed. Thus, Apotex will suffer an actual injury-in-fact if this case is dismissed without a finding of non-infringement or invalidity of the accused patents.

In its reply brief in the *Watson Laboratories* case, Merck argued that Watson Laboratories ("Watson") would not be prejudiced by a dismissal with prejudice since a dismissal with prejudice, along with a covenant not to sue, acts as a "triggering event." While there may have been some support for this assertion at one time, it is no longer true

today. The FDA recently ruled that a triggering "court decision" must include an "actual 'holding'...evidenced by language on the face of the court's decision showing that the determination of invalidity, noninfringement, or unenforceability has been made by the court." *Apotex, Inc. v. Food & Drug Administration*, 449 F.3d 1249, 1251 (D.C.Cir. 2006) (quoting Letter from Gary Buehler, Dir., Office of Generic Drugs, to Tammy McIntire, Apotex Corp. at 1-2 (April 11, 2006)). Thus, a stipulation of dismissal for lack of subject matter jurisdiction based upon the patent holder's statement that it had no intent to sue the generic manufacturer was not a triggering "court decision." *Id.* The FDA's ruling was upheld by the D.C. Circuit. *Id.* at 1252. Accordingly, a dismissal with prejudice, along with a covenant not to sue, will not constitute a "triggering event" under the most recent ruling by the FDA, which was upheld by the D.C. Circuit.

Second, Apotex's injury is directly traceable to Merck. Merck elected to file suit against Apotex. It did not sit passively by for 45 days, after which time Apotex might have filed a declaratory judgment suit. Instead, Merck sought the jurisdiction of the Court by filing suit within 45 days of receiving Apotex's paragraph IV certification letter. After deciding its claims would not be successful, Merck presented Apotex with a covenant not to sue and now seeks a voluntary dismissal to avoid an adverse judgment by this Court that would constitute the triggering event Apotex needs to enter the market.

Third, Apotex's injury can be redressed by this Court. Apotex merely requires a decision by this Court that would find that Merck's patents are either invalid or not infringed. If the Court denies Merck's motion to dismiss, Apotex will seek to file a summary judgment motion on invalidity and/or noninfringement. Based on Merck's covenant not to sue, Merck will be hard pressed to make a case that Apotex infringes any

of the asserted patents. If Apotex prevails on summary judgment, the Court's decision would constitute the triggering event that Apotex needs to enter the market on February 6, 2008 (assuming the "court decision" occurs at least 180 days prior to February 6, 2008). Thus, all three parts of the Supreme Court's test for a case or controversy are satisfied and this Court therefore has subject matter jurisdiction.

Merck has argued that the Federal Circuit's two-part declaratory judgment test is not satisfied because there is no reasonable apprehension by Apotex that it will face an infringement suit in light of the covenant not to sue granted by Merck.[11] The Federal Circuit's "reasonable apprehension" requirement is not required by the constitution but is a prudential test that fits most, but not all, patent infringement actions.

In *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997), the Federal Circuit cautioned that "[s]atisfication of this traditional two-part test is not, however, a prerequisite to jurisdiction in every possible patent declaratory judgment action." The two elements "merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement." *Id.*

---

[11] The Federal Circuit has a two-part test for determining whether there is an "actual controversy" in suits requesting a declaration of patent noninfringement or invalidity. "[T]here must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999); *EMC Corp.*, 89 F.3d at 811. There is no question that the filing of Apotex's ANDA constitutes an act of infringement. *See Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1328 (Fed. Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 990 (Fed. Cir. 2005), *cert denied*, 126 S.Ct. 473 (2005); 35 U.S.C. §271(e)(2).

In the present case, there is a real controversy over whether Merck's patents are invalid or not infringed that is not mooted by Merck's covenant not to sue because only a court decision finding the patents invalid or not infringed can constitute a "triggering event." Furthermore, the parties have adverse interests in creating a triggering event. Apotex desires a triggering event so its entry into the market will not be delayed. Merck wants to avoid a triggering event because it wants to maintain its market share and keep prices high for as long as possible. The Federal Circuit's two-part test and the focus on reasonable apprehension of suit ignores the injury suffered by Apotex from the bottleneck that delays it from marketing its product.

The Federal Circuit's rigid two-part test used to determine if there is jurisdiction under the Declaratory Judgment Act in a patent suit will soon be before the U.S. Supreme Court. The Supreme Court has granted certiorari in *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005), *cert. granted*, 126 S.Ct. 1329, 74 U.S.L.W. 3457 (U.S. Feb. 21, 2006) (No. 05-608), and it will be argued on October 4, 2006. The question presented in *MedImmune* is whether Article III's "actual controversy" requirement as implemented in the Declaratory Judgment Act, requires a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed.

The Solicitor General's Office submitted an amicus brief arguing that the Federal Circuit's restrictive test to determine the existence of an "actual controversy" in declaratory judgment cases is not warranted by Article III of the Constitution. *See* Brief for The United States As Amicus Curiae Supporting Petitioner at 8, *MedImmune, Inc. v. Genetech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005) (No. 05-608) (Ex. J hereto). The question

in determining whether there is an "actual controversy" under the Declaratory Judgment Act instead turns on whether the parties are involved in a substantial controversy that is sufficiently concrete and real that the court can resolve it through declaratory relief. *Id.*

If the Supreme Court agrees with the Solicitor General's Office, that ruling would further support finding subject matter jurisdiction in this case, aside from the collateral consequences doctrine and manipulation of jurisdiction issue discussed above, which on their own establish why this case should not be dismissed. The parties' controversy over the validity and infringement of Merck's patents, and Apotex's interest in triggering the 180-day exclusivity period of the first generic applicant in order to secure approval of its ANDA, is sufficiently concrete and real and the Court can resolve it through declaratory relief.

The Supreme Court has also sought the Solicitor General's views in *Apotex, Inc. v. Pfizer Inc.*, 385 F.Supp.2d 187 (S.D.N.Y. 2005), *aff'd*, 159 Fed.Appx. 1013 (Fed. Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3476 (U.S. Feb. 9, 2006) (No. 05-1006).[12] The Federal Circuit did not issue an opinion in the *Apotex, Inc. v. Pfizer Inc.* case because while that case was pending, the court decided *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005), *reh'g and reh'g en banc denied*, 405 F.3d 990 (Fed. Cir. 2005), *and cert. denied*, 126 S.Ct. 473 (2005). Both of those cases concern the justiciability of a generic manufacturer's declaratory judgment action against the brand name drug company after the brand name drug company failed to sue. In *Teva*, the Federal Circuit held that there was no subject matter jurisdiction under the Declaratory

[12] As of the filing of this brief, the Solicitor General's Office had not yet made its submission.

Judgment Act because there was no "reasonable apprehension of imminent suit." *Teva*, 395 F.3d at 1334.

The *Apotex v Pfizer* and *Teva v. Pfizer* cases involved the strategy where the brand name company declined to sue a subsequent generic filer, resulting in the generic's filing of a declaratory judgment action in order to obtain the necessary "court decision" triggering event. The present case is distinguishable because Merck filed suit first and then sought dismissal to avoid creating a triggering event. Thus, this case is more like 3M where the district court declined to allow the plaintiff to manipulate the district court's jurisdiction in that fashion.

Furthermore, there were two dissenting opinions denying rehearing en banc in the *Teva* case, one by Judge Gajarsa and the other by Judge Dyk. Both dissents recognized the bottleneck that secondary ANDA applicants faced in obtaining FDA approval when they were not sued. *See Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 405 F.3d 990, 994 & 998 (Fed. Cir. 2005). Both argued that an actual controversy existed over Teva's right to secure approval of its ANDA without being blocked by the first ANDA's 180-day exclusivity period. The Federal Trade Commission also filed amicus briefs in the *Teva* case in support of Teva's position that there was a justiciable controversy under those recurring facts. *See* Brief of Amicus Curiae Federal Trade Commission Supporting Appellant and Urging Reversal, *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.* (No. 04-1186) (Ex. K hereto); Brief of Amicus Curiae Federal Trade Commission Supporting Appellant's Combined Petition For Rehearing And Rehearing En Banc, *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.* (No. 04-1186) (Ex. L hereto). If the Supreme

Court grants certiorari in *Apotex v. Pfizer*, its ruling could have great importance to this case.

The Supreme Court could rule in either *MedImmune* or *Apotex v. Pfizer*, if it grants certiorari in the latter, that the Federal Circuit's two-part test to decide whether there is an actual controversy for a declaratory judgment action is too rigid, and that a "reasonable apprehension of suit" is not constitutionally mandated. Such a result would support Apotex's claim in this case that there is an actual controversy over whether Merck's patents are invalid or not infringed notwithstanding Merck's covenant not to sue.

Even if this Court felt constrained by the Federal Circuit's "reasonable apphrension" requirement, it could nonetheless rule that the case is not moot because of the collateral legal consequences of Apotex's right to trigger the 180-day exclusivity period of the first generic applicant. Moreover, the Court may decide it should exercise jurisdiction to prevent Merck from manipulating this Court's jurisdiction in order to avoid an adverse judgment.

CONCLUSION

For the foregoing reasons, Merck's motion to dismiss for lack of subject matter jurisdiction in light of Merck's covenant not to sue should be denied.

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Dated: August 29, 2006
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on August 29, 2006, the attached document was hand delivered on the following person and was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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EXHIBIT A

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(Cite as: Not Reported in F.Supp.2d)

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Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court,D. Delaware.

MARTEK BIOSCIENCES CORPORATION, Plaintiff,

v.

NUTRINOVA INC., Nutrinova Nutrition Specialties & Food Ingredients GMBH, Celanese Ventures GMBH, and Celanese AG, Defendants.

No. Civ.A. 03-896 GMS.

Oct. 8, 2004.

Steven J. Balick, Ashby & Geddes, Wilmington, DE, for Plaintiff.

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MEMORANDUM

SLEET, J.

I. INTRODUCTION

*1 The plaintiff, Martek Biosciences Corporation ("Martek"), filed the above-captioned action against Nutrinova Inc. and Nutrinova Nutrition Specialties & Food Ingredients GMBH (collectively, "Nutrinova") on September 23, 2003.[FN1] In its complaint, Martek alleges that the defendant is infringing United States Patent Nos. 6,607,900 (the " '900 patent") and 6,451,567 (the " '567 patent").

FN1. Celanese Ventures GMBH and Celanese AG have been dismissed as defendants in this case.

Presently before the court is Martek's motion to strike paragraph 26 of the affirmative defenses, and to dismiss paragraph 48 of Count I and Count III of Nutrinova's counterclaim.[FN2] For the following reasons, the court will deny Martek's motion to strike, but grant Martek's motion for a more definite statement. In addition, the court will grant in part and deny in part Martek's request to dismiss Count III of Nutrinova's counterclaim.

FN2. Martek titles its motion as a motion to strike. However, in its Opening Brief in support of the motion (D.I.12), Martek requests, in the alternative, that the court require Nutrinova to provide a more definite statement pursuant to Rule 12(e) of the Federal Rules of Civil Procedure. The court will consider both of Martek's motions.

II. BACKGROUND

Martek is a Delaware Corporation that develops and sells products from microalgae, including nutritional fatty acids such as the omega-3 fatty acid, docosahexaenoic acid ("DHA"). This case involves two of Martek's patents relating to DHA. DHA is a major and essential structural fatty acid, necessary for the development of organs including the eye retina, the brain, and the heart. The human body produces DHA in only limited quantities, creating a need in the medical science community to find alternate sources of DHA or develop processes to produce it. Martek recognized this need and developed microalgae processes to make DHA and products relating to its processes. Its patent portfolio consists of nearly fifty United States patents as well as foreign patents, including many directed to its DHA products.

Nutrinova is a Delaware Corporation that developed a microalgae process to make DHA, and currently markets its product under the brand name DHActive0. After Nurtinova began marketing DHActive0, Martek initiated discussions with Nutrinova regarding its potentially infringing activities. On May 27, 2003, Martek sent an email to Nutrinova, citing its patent portfolio and requesting to discuss the situation. (D.I.13, Exh. 2). Nutrinova replied, requesting information regarding the patents and claims that Martek believed Nutrinova was potentially infringing. On June 18, 2003, Martek responded, via email, citing eighteen specific patents from its portfolio that it believed were relevant to the discussions. (*Id.* Exh. 4). Nutrinova reviewed the list and concluded that the patents offered by Martek were either not infringed or were invalid. Nutrinova then requested a meeting with Martek to discuss the situation further. (*Id.* Exh. 5) According to Martek, the parties were unable to amicably settle the matter. On September 23, 2003, Martek filed its complaint.

III. STANDARDS OF REVIEW

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A. Rule 12(f)

Rule 12(f) of the Federal Rules of Civil Procedure allows a court to strike "any insufficient defense" from any pleading. Motions to strike affirmative defenses are disfavored. *Proctor & Gamble Co. v. Nabisco Brands, Inc.*, 697 F.Supp. 1360, 1362 (D.Del.1988). When ruling on such a motion, "the [c]ourt must construe all facts in favor of the nonmoving party ... and deny the motion if the defense is sufficient under the law." *Id.* Furthermore, courts prefer not to grant a motion to strike "unless it appears to a certainty that ... [the movant] would succeed despite any statement of the facts which could be proved in support of the defense." *Greiff v. T.I.C. Enterprises, L.L.C.*, No. Civ. 03-882, 2004 WL 115553 (D.Del. Jan. 9, 2004).

B. Rule 12(e)

***2** Rule 12(e) allows a party to move for a more definite statement when a pleading is "so vague or ambiguous that the party cannot reasonably be required to frame a responsive pleading." Fed. R. Civ. P. 12(e); *see Schaedler v. Reading Eagle Publication*, 370 F.2d 795, 798 (3d Cir.1967) (same). Courts have interpreted this language to mean that the motion should only be granted where the pleading is unintelligible, *see CFMT, Inc. v. Yieldup International Corp.*, No.CIV.A.95-549, 1996 WL 33140642, at *1 (D.Del. Apr.5, 1996); *United States v. Bd. of Harbor Comm'rs*, 73 F.R.D. 460, 462 (D.Del.1997), or the issues cannot be determined. *See Fischer & Porter Co. v. Sheffield Corp.*, 31 F.R.D. 534, 536 (D.Del.1962). Courts have also granted the motion where the pleading has failed to satisfy the heightened pleading requirements of Rule 9(b). *See EMC Corp. v. Storage Tech. Corp.*, 921 F.Supp. 1261 (D.Del.1996).

C. Rule 12(b)(1)

A motion to dismiss for lack of subject matter jurisdiction, pursuant to Rule 12(b)(1), challenges the jurisdiction of the court to address the merits of a plaintiff's complaint. A motion to dismiss under Rule 12(b)(1) for lack of subject matter jurisdiction can take two forms: it can attack the complaint on its face (facial attack), or it can attack the existence of subject matter jurisdiction in fact (factual attack). *Mortensen v. First Federal Savings and Loan*, 549 F.2d 884, 891 (3d Cir.1977). When reviewing a facial attack the court must consider the allegations of the complaint as true, making all reasonable inferences in the plaintiff's favor. *Id. See also Barrister v. Wendy's Int'l, Inc.*, 1993 WL 293896, *3 (E.D.Pa. July 30, 1993).

When reviewing a factual attack, however, the court is free to weigh evidence outside the pleadings to resolve factual issues bearing on jurisdiction and to satisfy itself as to the existence of its power to hear the case. *Mortensen*, 549 F.2d at 891. Therefore, no presumptive truthfulness attaches to the plaintiff's allegations, and the existence of disputed material facts will not preclude the court from evaluating the merits of jurisdictional claims for itself. *Id.* The plaintiff bears the burden to prove that jurisdiction does in fact exist. *Id.* However, the plaintiff's burden is relatively light, since "dismissal for lack of jurisdiction is not appropriate merely because the legal theory alleged is probably false, but only because the right claimed is 'so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as to not involve a federal controversy.' " *Kulick v. Pocono Downs Racing Ass'n*, 816 F.2d 895, 899 (3d Cir.1987) (quoting *Oneida Indian Nation v. County of Oneida*, 414 U.S. 661, 666, 94 S.Ct. 772, 39 L.Ed.2d 73 (1974)).

IV. DISCUSSION

A. Paragraph 26 of Nutrinova's Affirmative Defenses and Paragraph 48 of Nutrinova's Counterclaim [FN3]

FN3. Paragraph 26 of the affirmative defenses states:
26. The '567 patent is unenforceable, because of the applicants' inequitable conduct in the prosecution of the patent. In particular, Martek prepared, filed and prosecuted a patent application, Serial Number 07/580,778 filed on September 11, 1990, which issued as the Martek '567 patent. That application was prepared, filed and prosecuted with material false data. The applicants knew that the application contained false data, but nevertheless filed, continued to prosecute, and convinced the

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> Patent Office to issue the '567 patent based on such material false data. Such misconduct constitutes inequitable conduct, and renders the '567 patent and all affiliated patents unenforceable.
>
> Paragraph 48 of Count I of the counterclaim states:
>
> 48. The '567 patent is unenforceable, because the applicants' inequitable conduct in the prosecution of the patent. In particular, Martek prepared, filed and prosecuted a patent application, Serial Number 07/580,778 filed on September 11, 1990, (the "778 application"), which is a parent application from which Martek's '567 patent on its face claims priority. A claim for priority from the 778 application is also made in a declaration filed by the inventors in connection with the '567 patent. The 778 application was prepared, filed and prosecuted with material false data. The applicants knew that the application contained false data, but nevertheless filed, continued to prosecute, and convinced the Patent Office to issue the '567 patent based on such material false data. Such misconduct constitutes inequitable conduct, and renders the '567 patent and all affiliated patents unenforceable.

As one of its affirmative defenses, Nutrinova alleges that Martek engaged in inequitable conduct in acquiring the '567 patent. Martek moves to strike the defense, as well as paragraph 48 of Nutrinova's counterclaim, which is predicated on the inequitable conduct defense, on the grounds that they do not meet the pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. Specifically, Martek claims that the language in Nutrinova's affirmative defense and counterclaim fails to provide any specifics concerning Martek's inequitable conduct in obtaining the '567 patent. In response, Nutrinova asserts that its pleading is not "vague or conclusory." Further, Nutrinova asserts that there is no authority that requires a pleading that claims inequitable conduct to identify specific falsified data, describe why it is false, or state why it was material, as Martek suggests it should have done.

*3 The parties do not dispute that the particularity requirement of Rule 9(b) applies to inequitable conduct charges. In the context of alleged inequitable conduct before the PTO during a patent prosecution, Rule 9(b) does not require that a party plead the "date, place or time" of the fraud, so long as that party uses an "alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir.1984), *cert denied*, 469 U.S. 1211, 105 S.Ct. 1179, 84 L.Ed.2d 327 (1985); *see EMC Corp. v. Storage Tech. Corp.*, 921 F.Supp. 1261, 1262-63 (D.Del.1996). Nutrinova's pleadings do not pass the *Seville* test. Even if Nutrinova did not have to describe why the data Martek submitted to the Patent Office was false or state why that data was material, it should have identified the data in its affirmative defense and counterclaim.[FN4] The court, therefore, finds that Nutrinova has failed to plead facts with sufficient particularity in paragraph 26 of its affirmative defenses and paragraph 48 of its counterclaim to establish a charge of inequitable conduct based on Martek's alleged submission of false data during the prosecution of the '567 patent.[FN5]

> FN4. The court notes that Nutrinova provided a more detailed description of its inequitable conduct claim in a letter to Martek, stating that Martek's patent application "contains examples which do not represent actual data, and they are written in past tense." (D.I.13, Exh. 1). The court will not determine whether the information contained in Nutrinova's letter is sufficient to meet the Rule 9(b) pleading requirements. The court uses the letter only to point out that Nutrinova possesses more detailed information regarding Martek's alleged inequitable conduct.
>
> FN5. Because Nutrinova has not adequately pled its inequitable conduct claim, its pleading cannot be salvaged by future discovery. *EMC Corp.*, 921 F.Supp. at 1264 (concluding that the plaintiff could not "use its interrogatory responses to fulfill the particularity requirements of Rule 9(b)").

In the present case, it does not appear to a certainty that Martek would succeed despite any statement of facts which could be proved in support of Nutrinova's inequitable conduct defense. Thus, the court does not conclude that the proper remedy in this case is to strike Nutrinova's pleadings.

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However, Martek has requested, in the alternative, that the court require Nutrinova to provide a more definite statement. The court finds that Nutrinova's inequitable conduct pleadings fail to satisfy the Rule 9(b) requirements in that they are so vague and ambiguous that Martek cannot draft a responsive pleading. Therefore, the court will grant Martek's request for a more definite statement.

B. Count III of Nutrinova's Counterclaim

Martek next asserts that the court should dismiss Count III of Nutrinova's counterclaim for lack of subject jurisdiction. In its motion, Martek attacks Nutrinova's complaint on factual grounds. Thus, the court will consider evidence outside of the pleadings to determine whether subject matter jurisdiction exists. Nutrinova has the burden of proving that jurisdiction exists and must demonstrate that its claim is not wholly insubstantial, frivolous, devoid of merit, or made for the purpose of obtaining jurisdiction. *See Kulick*, 816 F.2d at 899. Count III is a declaratory judgment claim.[FN6] Martek argues that the facts of the case do not give rise to declaratory judgment jurisdiction. The Declaratory Judgment Act provides:

> FN6. Martek reproduces all of Count III in its Opening Brief in support of its motion (D.I. 12, at 7). The court, however, will paraphrase the language. Count III entitled, Non-Liability as to DHActive0 and Nutrinova Process, essentially asks the court to conclude that Nutrinova's activities do not infringe and that it is not liable for infringement of any valid and enforceable right of Martek, including any valid and enforceable claim of any issued United States patent owned by Martek.

In a case of actual controversy within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

*4 28 U.S.C. § 2201(a). The federal courts have jurisdiction over a declaratory judgment action only if an "actual controversy" exists between the parties at the time the plaintiff files its complaint and throughout the pending action. *Shell Oil Co. v. Amoco Corp.*, 870 F.2d 885, 887 (Fed.Cir.1992).

In the patent context, the United States Court of Appeals for the Federal Circuit has articulated a two-part test to determine whether an actual controversy exists: (1) an explicit threat or other act by the patentee creating in the declaratory plaintiff a reasonable apprehension that the patentee will initiate suit; and (2) present activity which could constitute infringement or concrete steps taken with the intent to infringe. *BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed.Cir.1993). Martek asserts that Nutrinova does not satisfy the first prong of *BP Chemicals* because Nurtinova's broad claims do not cite the specific patents or rights at issue, and could potentially encompass all of Martek's intellectual property, including its nearly fifty U.S. patents and its non-patent intellectual property rights. In addition, Martek contends that Nutrinova has not alleged, and cannot allege, facts necessary to establish that Martek's conduct placed Nutrinova in reasonable apprehension of an infringement suit over such broad subject matter. Lastly, Martek asserts that even if the court determines that an actual controversy exists, considerations of justice and efficiency require the court to decline declaratory judgment jurisdiction over Count III.[FN7]

> FN7. The court's exercise of jurisdiction over a declaratory judgment action is discretionary. *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed.Cir.1991).

Nutrinova argues that its declaratory judgment counterclaim is not broad and open-ended because it seeks a declaration only as to the one specific product, DHActive0, made by the one specific process that is the subject of Martek's complaint. Nutrinova further argues that an actual controversy exists because Martek has already brought a suit for infringement against it for making DHActive0. Moreover, Nutrinova contends that even if Martek had not initiated this lawsuit, its written assertions to Nutrinova constitute a basis for a declaratory judgment action under *Dainippon Screen Mfg. Co. v. CFMT, Inc.*, 142 F.3d 1266 (Fed.Cir.1998) (affirming jurisdiction because a voice-mail to the defendant, stating that the patentee intended to protect its rights, created a reasonable apprehension in the defendant that the patentee would sue).

The parties do not dispute whether there is "present activity

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which could constitute infringement." FN8 Thus, the court must determine whether Martek's conduct has been such that it caused Nutrinova to have an objectively reasonable apprehension of being sued by Martek at the time the declaratory judgment action was filed. In making its determination, the court must consider the totality of the circumstances. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 (Fed.Cir.1992).

> FN8. Nevertheless, the court finds that Nutrinova satisfies the "present activity" prong of *BP Chemicals* because it engages in the manufacture and production of DHActive0, which is sufficiently similar to Martek's patents. *See Millipore Corp. v. Univ. Patents, Inc.*, 682 F.Supp. 227, 232 (D.Del.1987).

The court agrees with Nutrinova that the litigious history between the parties and Martek's written assertions weigh in favor of a finding that Nutrinova has a reasonable apprehension of suit. The Federal Circuit has stated that "the question is whether the relationship between the parties can be considered a 'controversy,' and that inquiry does not turn on whether the parties have used particular 'magic words' in communicating with one another." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 812 (Fed.Cir.1996). The court also cautioned that the "test for finding a 'controversy' ... is a pragmatic one and cannot turn on whether the parties use polite terms in dealing with one another or engage in more bellicose saber rattling." *Id*

*5 In the present case, even though Martek did not explicitly threaten to bring an infringement suit in any correspondence with Nutrinova, the court concludes that Martek's June 18, 2003 email (D.I.13, Exh. 4) created a reasonable apprehension in Nutrinova that Martek would sue. In fact, Martek filed its complaint on September 23, 2003, approximately three months after its email to Nutrinova and one month after Nutrinova's request for a meeting. Nevertheless, Martek's June 18, 2003 email included a list of eighteen of its nearly fifty U.S. patents that it selected as relevant to Nutrinova's conduct. Beyond that, the email discussed Martek's patents and patent portfolio in a general sense. Martek's email created a reasonable apprehension in Nutrinova that Martek only would sue for infringement of one or more of the eighteen listed patents, not "any" or all of its patents. Thus, Nutrinova's claim for non-liability as to "any valid and enforceable claim of any issued United States patent owned by Martek," and "any valid and enforceable right of Martek" is too broad. Only those patents referenced in the June 18, 2003 email are proper subjects for Nutrinova's declaratory judgment claim. The court, therefore, will dismiss Count III of Nutrinova's counterclaim as it relates to Martek patents other than the eighteen listed in the June 18, 2003 email.

ORDER

For the reasons stated in the court's Memorandum Opinion of this same date, IT IS HEREBY ORDERED that:

1. The plaintiff's Motion to Strike Paragraph 26 of the Affirmative Defenses and Dismiss Paragraph 48 of Count I and Count III of the Counterclaims by Nutrinova and Nutrinova Specialties & Food Ingredients GMBH (D.I.11) is GRANTED in part and DENIED in part.

2. The plaintiff's Motion, in the alternative, For a More Definite Statement (D.I.12) is GRANTED.

D.Del.,2004.
Martek Biosciences Corp. v. Nutrinova Inc.
Not Reported in F.Supp.2d, 2004 WL 2297870 (D.Del.)

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EXHIBIT B

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Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2004 WL 769365 (D.Del.)
(Cite as: Not Reported in F.Supp.2d)

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Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court,D. Delaware.

MEDTRONIC AVE, INC., Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION, Scimed Life Systems, Inc., Boston Scientific Scimed, Inc., and Medinol, Ltd., Defendants.

No. Civ. 98-478-SLR.

April 5, 2004.

Karen Jacobs Louden, Philip Bangle, Morris, Nichols, Arsht & Tunnel, Wilmington, Delaware; Raphael V. Lupo, Donna M. Tanguay, Mark G. Davis, McDermott, Will & Emery, Washington, D.C., for Plaintiff.

Josy W. Ingersoll, Sara Beth A. Reyburn, Young Conaway Stargatt & Taylor, LLP, Wilmington, Delaware, for Defendants.

Christopher A. Hughes, Richard C. Komson, Dorothy R. Auth, Morgan & Finnegan, New York, New York, for Medinol Ltd.

MEMORANDUM OPINION

ROBINSON, Chief J.

I. INTRODUCTION

*1 On August 13, 1998, Arterial Vascular Engineering, Inc. filed a complaint against Boston Scientific Corporation ("BSC") and Scimed Systems Inc. alleging willful infringement of U.S. Patent Nos. 5,291,331 and 5,674,278 (collectively "the Boneau patent) by the NIR model stents. (D.I.1) On June 28, 2000, Medtronic AVE, Inc. ("Medtronic") [FN1] filed a second amended complaint to add Boston Scientific SciMed, Inc. and Medinol, Ltd. ("Medinol") as defendants in the infringement action. (D.I 62) Medtronic also asserted a third patent, namely, U.S. Patent No. 5,879,382, and added claims for contributory and inducing infringement to the suit.[FN2] (*Id.* at ¶ 12)

FN1. Arterial Vascular Engineering, Inc. amended its complaint on March 11, 1999 to substitute Medtronic AVE as the plaintiff. (*See* D.I. 17)

FN2. With particular regard to Medinol, Medtronic asserts:

On information and belief [d]efendant Medinol through its licensing, manufacturing and subsequent sale of the NIR model stents has actively, intentionally and knowingly assisted [d]efendants Boston Scientific and SciMed in direct infringement of the [Boneau] patents.

On information and belief [d]efendant Medinol has been aware of the [Boneau] patents and knew that direct infringement of the [Boneau] patents was likely to occur as a result of its sale to [d]efendant Boston Scientific of the NIR model stents for distribution in the United States.

(*Id.* at ¶¶ 18, 19)

On July 13, 2000, Medinol answered the second amended complaint, denied all infringement allegations, and asserted numerous affirmative defenses. (D.I.50) Medinol also filed a counterclaim for a declaratory judgment of invalidity, unenforceability, and noninfringement. (*Id.*)

Medtronic is a corporation organized under the laws of the State of Delaware with its principal place of business in Santa Rosa, California. (Id. at ¶ 1) Medtronic manufactures specialized stent delivery systems used in coronary and peripheral applications in the human body. (*Id.*) Medinol is an Israeli corporation with its principal place of business in Tel Aviv, Israel. (Id. at ¶ 5) Medinol manufactures and sells medical devices, including stents, that are used in the United States. (*Id.*)

Presently before the court is Medinol's motion to dismiss Medtronic's second amended complaint for lack of subject matter jurisdiction. (D.I.137) For the reasons that follow, the court denies this motion.

II. BACKGROUND

Medinol entered into a supply agreement with BSC on October 25, 1995. (D.I. 139 at ¶ 3) Medinol agreed to exclusively supply BSC with NIR stents to sell in all countries of the world. (*Id.*) Under the terms of the agreement, Medinol performed the NIR stent manufacture at its operation in Jerusalem, Israel and then delivered the stents to locations se-

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lected by BSC. (*Id.*) On numerous occasions, BSC directed Medinol to ship NIR stents to its facility in Galway, Ireland ("BSC-Ireland") where BSC finished the stents, repackaged them, and shipped them to its plant in Maple Grove, Minnesota. (*Id.*) There, BSC assembled the NIR stents into its balloon catheter delivery systems for sale in the United States. Title and ownership of the NIR stents passed from Medinol to BSC pursuant to the supply agreement. Section 3.05 states:

Shipment of [s]tents purchased by BSC from Medinol shall be F.C.A. at Medinol's facility for delivery to such of BSC's facilities as BSC shall from time to time designate. All freight, insurance and other shipping expenses relating to such stents, as well as any packing expenses, shall be borne licensed by BSC. Title to and risk of loss for stents purchased by BSC shall pass to BSC upon delivery to the carrier for shipment to BSC or BSC's designated ship destination.

***2** (D.I. 157 at 3) Around February 2002, Medinol terminated the supply agreement and discontinued shipping NIR stents to BSC in May 2002. (D.I. 139 at ¶ 3)

III. STANDARD OF REVIEW

Medinol moves for dismissal for lack of subject matter jurisdiction, presumably pursuant to Federal Rule of Civil Procedure 12(b)(1). In doing so, Medinol attached materials outside the pleadings to its motion. When such occurs, the court normally treats the motion to dismiss as one for summary judgment. In the case at bar, however, the court will treat Medinol's motion as a motion to dismiss because the court may consider materials outside the pleadings when adjudicating the question of subject matter jurisdiction. *See Lear v. Apfel*, 2001 WL 179861, *1 n. 1 (E.D.Pa.2001) (citations omitted). Indeed, a motion to dismiss under Rule 12(b)(1) is the appropriate vehicle to adjudicate the procedural question of subject matter jurisdiction rather than a motion for summary judgment, which goes to the merits of an action. *See Brittingham v. Barnhart*, 2003 U.S. Dist. LEXIS 20869, *2 (D.Del.2003) (citing *Freeman v. Herman*, 1998 WL 813426, *2 (E.D.Pa.1998)). In performing such adjudication pursuant to Rule 12(b)(1), "the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *Brittingham*, 2003 U.S. Dist. LEXIS at *2. Moreover, contrary to Medtronic's assertion, "the fact that matters outside the pleadings are considered does not transform a Rule 12(b)(1) motion to dismiss into a motion for summary judgment." *Id.*

IV. DISCUSSION

A subject matter jurisdiction attack pursuant to Rule 12(b)(1) challenges the court's jurisdiction to address the merits of the complaint. *See Lieberman v. Delaware*, 2001 WL 1000936, at *1 (D.Del.2001). A party may raise the lack of subject matter jurisdiction at any time; it cannot be waived. Fed.R.Civ.P. 12(h)(3). In fact, the court is obliged to address the issue on its own motion if not raised by the parties. *See Neiderhiser v. Berwick*, 840 F.2d 213, 216 (3d Cir.1988). Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence. *See Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 69 (3d Cir.2000).

There are two types of Rule 12(b)(1) motions. The first type, a facial attack, challenges the legal sufficiency of the claim. *Mortensen v. First Fed. Sav. and Loan*, 549 F.2d 884, 891 (3d Cir.1977). Under this type of challenge, the court must accept as true the allegations contained in the complaint. *See* 2 James W. Moore, Moore's Federal Practice § 12.30[4] (3d ed.1997). Dismissal for a facial challenge is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or ... is wholly insubstantial and frivolous.' " *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408-1409 (3d Cir.1991) (quoting *Bell v. Hood*, 327 U.S. 678, 682 (1946)).

***3** The second type, a factual attack, challenges the sufficiency of a jurisdictional fact (i.e., it allows the court to question the plaintiff's facts after the defendant files an answer). *Mortensen*, 549 F.2d at 891. Since Medinol filed an answer to the complaint, the instant attack on subject matter jurisdiction is necessarily considered a factual type of challenge. In such situation, the court is not "confine[d] to allegations in the ... complaint, but [can] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir.1997); *see also Mortensen*, 549 F.2d at 891-892. "No presumptive truthfulness attaches to plaintiff's allegations,

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and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Carpet Group*, 227 F.3d at 69 (quoting *Mortensen*, 549 F.2d at 891). Although the court should determine subject matter jurisdiction at the outset of a case, "the truth of jurisdictional allegations need not always be determined with finality at the threshold of litigation." Moore at § 12.30[1]. In other words, "[n]ormal practice permits a party to establish jurisdiction at the outset of a case by means of a nonfrivolous assertion of jurisdictional elements, ... and any litigation of a contested subject-matter jurisdictional fact issue occurs in comparatively summary procedure before a judge alone (as distinct from litigation of the same fact issue as an element of the cause of action, if the claim survives the jurisdictional objection)." *Jerome B. Grubart, Inc. v. Great Lakes Dredge & Dock Co.*, 513 U.S. 527, 537-38 (1995) (citations omitted).

Medtronic bases subject matter jurisdiction on federal question jurisdiction pursuant to 28 U.S.C. § 1331 and original jurisdiction under patent laws pursuant to 28 U.S.C. § 1338(a). (*See* D.I. 62 at ¶ 8) There is no dispute that Medinol delivered NIR stents to BSC-Ireland. Medtronic further contends, however, that Medinol also delivered stents to the United States, specifically to BSC's Minnesota facilities. Medtronic likewise asserts that Medinol engaged in many supply and pricing communications with BSC. Medtronic charges that these communications occurred between BSC personnel located in the United States as opposed to BSC personnel located in Ireland. Medtronic claims that Medinol participated in efforts to secure regulatory approval for the NIR stents in the United States, consistent with the supply agreement. In response, Medinol argues that it has not committed any act of alleged infringement in the United States as required by the provisions of 35 U.S.C. § 271. It avers that all NIR stent deliveries were made outside the U.S. to BSC-Ireland. Medinol contends, therefore, that it should be dismissed from the case.

The court disagrees with Medinol. Congress invested original subject matter jurisdiction over patent infringement actions under 35 U.S.C. § 271 in the federal district courts. In pertinent part, 28 U.S.C. 1338(a) states:

*4 The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.

The Supreme Court has explained that "when the plaintiff bases his cause of action upon an act of Congress, jurisdiction cannot be defeated by a plea denying the merits of the claim." *The Fair v. Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1912). The court is not prepared to decide on the record presently before it whether Medinol engaged in the alleged infringing activities in the United States. Because subject matter jurisdiction cannot be waived, the court denies Medinol's motion to dismiss without prejudice to renew at the completion of discovery upon a fully developed factual record.

V. CONCLUSION

For the reasons stated, the court denies Medinol's motion to dismiss for lack of subject matter jurisdiction. An order shall issue.

D.Del.,2004.
Medtronic Ave, Inc. v. Boston Scientific Corp.
Not Reported in F.Supp.2d, 2004 WL 769365 (D.Del.)

Briefs and Other Related Documents (Back to top)

• 2000 WL 34417250 (Trial Pleading) Answer to Second Amended Complaint, Affirmative Defenses and Counterclaims (Jul. 13, 2000)

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EXHIBIT C

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Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2005 WL 1323435 (N.D.Ill.)
(Cite as: Not Reported in F.Supp.2d)

Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court,N.D. Illinois, Eastern Division.

ABBOTT LABORATORIES Plaintiff,

v.

ANDRX PHARMACEUTICALS, INC., Teva Pharmaceuticals USA, Inc., and Roxane Laboratories, Inc. Defendants.

No. 05 C 1490.

June 3, 2005.

Edward L. Foote, Michael Alan Flomenhoft, R. Mark McCareins, Todd Jay Ehlman, Winston & Strawn, Chicago, IL, Andrea Weiss Jeffries, Jeffrey I. Weinberger, Ted G. Dane, Munger, Tolles & Olson, LLP, Los Angeles, CA, Jennifer L. Polse, Munger Tolles & Olson LLP, San Francisco, CA, for Plaintiff.

Bruce Michael Gagala, Robert F. Green, Steven H. Sklar, David M. Airan, Robert F. Green, Leydig, Voit & Mayer, Ltd., Erik F. Dyhrkopp, Michael Sennett, Wonah Kim Ross, Bell Boyd & Lloyd, Kenneth G. Schuler, Amanda Jean Hollis, Latham & Watkins LLP, Chicago, IL, James Galbraith, Maria L. Palmese, Colman B. Ragan, Cynthia M. Lambert, Robert V Cerwinski, Kenyon & Kenyon, Steven C. Cherny, Latham & Watkins LLP, New York, NY, Matthew Rawlinson, Latham & Watkins LLP, Menlo Park, CA, for Defendants.

MEMORANDUM OPINION AND ORDER

COAR, J.

***1** This matter comes before the court on plaintiff Abbott Laboratories, Inc.'s ("Abbott") motion for a preliminary injunction against defendant Teva Pharmaceuticals USA, Inc. ("Teva"). Plaintiff seeks to enjoin Defendant Teva from marketing a generic version of the antibiotic drug, clarithromycin, in an extended release formulation. Abbott is the patent holder on a series of patents relating to clarithromycin, which Abbott markets under the brand name "BIAXIN" and, in its extended release formulation, "BIAXIN XL." Abbott alleges that Teva's generic product infringes Plaintiff's U.S. Patent Nos. 4,680,386 ("the '386 patent"); 6,010,718 ("the '718 patent"); and 6,551,616 ("the '616 patent"), relating to its BIAXIN XL product.

I. BACKGROUND

Abbott Laboratories filed a complaint against Andrx Pharmaceuticals, Inc. ("Andrx"), Teva Pharmaceuticals USA, Inc., and Roxane Laboratories, Inc. ("Roxane"), alleging patent infringement. Andrx, Teva, and Roxane manufacture and market generic versions of branded pharmaceuticals in the United States. Abbott sought a declaratory judgment that these defendants would infringe the '386 patent. In addition, Abbott sought a declaratory judgment against both Teva and Andrx of infringement of Abbott's United States Patent Nos. 6,551,616 ("the '616 patent"), 6,010,718 ("the '718 patent"), and 6,872,407 ("the '407 patent"). Each of these patents pertains to Abbott's branded antibiotic product, BIAXIN XL, which is an extended release formulation of clarithromycin, an erythromycin derivative.

Clarithromycin is a macrolide antibiotic used to treat bacterial infections, particularly those of the skin and upper respiratory system. Abbott held a patent on the immediate release version of clarithromycin, marketed as BIAXIN, until the patent expired on May 23, 2005. Abbott began marketing BIAXIN in the United States in approximately 1991. In 2000, Abbott was issued two formulation patents (the '616 and the '718 patents) on an extended release formulation of clarithromycin. Abbott began marketing this extended release formulation under the name BIAXIN XL in 2000. As of May 2005, Abbott estimated that BIAXIN XL accounted for approximately 70% of the sales in the BIAXIN market. Generic competitors entered the market for immediate release clarithromycin on May 24, 2005.

Abbott brought an application for a temporary restraining order against Andrx and Teva in this court. Andrx and Abbott entered a stipulated temporary restraining order on May 20, 2005. This court held a hearing and entered a temporary restraining order against Teva on May 20, 2005.[FN1] This court then held a hearing on Abbott's motion for a preliminary injunction against Teva.

> FN1. That TRO will expire of its own force on June 13, 2005.

Teva does not dispute that its generic clarithromycin extended release formulation infringes Abbott's '718 and '616 pat-

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ents. Rather, Teva asserts that those patents, along with the '386 patent, are invalid for obviousness under 35 U.S.C. § 103 (2004). In addition, Teva asserts that it does not infringe the '386 patent.

II. PRELIMINARY INJUNCTION STANDARD

*2 A party seeking a preliminary injunction must make a four-part threshold showing that (1) the movant has some likelihood of success on the merits of the underlying litigation; (2) immediate irreparable harm will result if the relief is not granted; (3) the balance of hardships to the parties weighs in the movant's favor; and (4) the public interest is best served by granting the injunctive relief. *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 973 (Fed.Cir.1996).

III. ANALYSIS

A. Likelihood of Success on the Merits

In order to show that it has a likelihood of success on the merits, in light of the burdens and presumptions that will be present at trial, the movant must first prove that the non-movant infringes the patents in suit, and also that the movant's infringement claim will likely survive the non-movant's challenges on the basis of patent invalidity and unenforceability. *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1364 (Fed.Cir.1997). A patent is presumed to be valid, 35 U.S.C. § 282 (2002), and at trial, the party raising a validity challenge must prove invalidity by clear and convincing evidence. This presumption does not relieve a patentee who moves for a preliminary injunction from carrying its normal burden of demonstrating a likelihood of success on all disputed liability issues at trial, including validity. *Id.* at 1364, n. 2. A validity challenge at the preliminary injunction stage can succeed on evidence that would not support a judgment of validity at trial. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1359 (Fed.Cir.2001). "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." *Id.* The alleged infringer must identify at least some persuasive evidence of invalidity at this early stage to overcome the presumption of validity. *Pharmacia & Upjohn Co. v. Ranbaxy Pharmaceuticals, Inc.*, 274 F.Supp.2d 597, 601 (N.D.Ill.2003). The patentee also is held to a less stringent standard and must only present a "clear case supporting the validity of the patent in suit." *Id.* A patentee can make such a case by showing, for example, that the patent in suit has withstood previous validity challenges in other proceedings or benefitted from a long period of industry acquiescence in its validity.

Abbott asserts that it is likely to succeed on the merits because it will likely prove infringement at trial of one or more of the claims of the patents-in-suit. Plaintiff also contends that it likely will demonstrate that Defendant's challenges to the validity of the patents in suit lack substantial merit. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed.Cir.2001).

1. *Infringement Analysis*

An infringement inquiry proceeds in two steps. *Pharmacia*, 274 F.Supp.2d at 601. First, the court must determine, as a matter or law, the correct scope and meaning of the disputed claim term. Then, the court must compare the properly construed claim to the accused device and ascertain whether that device contains *every* limitation of the claim or a substantial equivalent thereof. *Id.*

*3 There is a " 'heavy presumption' that a claim term carries its ordinary and customary meaning." *CCS Fitness Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed.Cir.2002). Claim terms should therefore be accorded their ordinary meaning unless the patentees "clearly set forth a definition of the disputed claim term in either the specification or prosecution history." *Id.* When interpreting an asserted patent claim, the court should look first to the intrinsic evidence of record, which is the patent itself, including its claims, specification, and complete prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995) (*en banc*), *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). This intrinsic evidence is the primary and most significant source of the legally operative meaning of any claim language that is in dispute. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed.Cir.1996). The court may also consider extrinsic evidence such as expert declaration evidence provided for the parties. *Pharmacia*, 274 F.Supp.2d at 602.

Abbott is the exclusive U.S. licensee of the '386 patent

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which discloses a compound (and the salts thereof) formed during the most commonly used process for the synthesis of 6-0-methylerythromycin, commonly known as clarithromycin. This compound is referred to in the patent as an "intermediate" for the preparation of clarithromycin. The compound itself is referred to as 6-0-methylerythromycin A 9-oxime ("9-oxime") and, according to the patent, "is useful in the preparation of clarithromycin and useful as an antibacterial agent." U.S. Pat. No. 4,680,386 at 1:5-10.

Abbott claims that 9-oxime is present in trace amounts in Teva's extended release clarithromycin product. Teva denies that 9-oxime is present in its product, but asserts that if it is present, the quantities are insignificant and cause no harm to Abbott (or benefit to Teva) and, finally, that the '386 patent is invalid because of obviousness.

At this early stage of the proceedings, the parties have raised no issue as to claim construction.

Teva resists Abbott's claim that its product infringes the '386 patent. Abbott's expert, Alexander Schilling, tested Teva's bulk product and found 9-oxime in the amount of one part per million (ppm). Teva's expert, George Gokel, disputes this finding and criticizes Schilling's methodology. The Court is not persuaded that Schilling's methodolology and finding are unreliable, especially in light of exhibit A to the Declaration of Jennifer L. Polse in Support of Abbott's Motion for a Preliminary Injunction against Teva. That exhibit appears to be a letter (on Teva letterhead) from Michaela Rapaport of the Regulatory Affairs Department, Teva, API Division to Mr. Moshe Nulman. The reference is: "RE: Impurity. Clarithromycin 9-oxime (CLM oxime)." In substance, the letter reads:

Please be informed that the impurity Clarithromycin 9-oxime (CLM oxime) will no longer be listed on the Certificate of Analysis. Furthermore, it will not be included in the official Drug Master File as a potential impurity. However, due to different regulatory considerations, the levels of this impurity will be monitored continually but will not officially be reported.

*4 This letter appears to represent an acknowledgment by Teva that 9-oxime is present in minute (impurity) amounts in Teva's product and the Court will so find.

As this court noted in a prior decision regarding a temporary restraining order, Teva apparently concedes that if the '718 and '616 patents are valid, it will be infringing them. For that reason, this court will turn directly to a validity analysis of those two patents

2. *Invalidity Defense-Obviousness*

Only a valid patent gives the patent owner the right to exclude others; an invalid patent cannot be infringed. For this reason, accused patent infringers often seek to demonstrate that the patentee's patent is invalid and that they cannot be held liable for infringement. One of the requirements for patentability is that a new and useful product or process be "nonobvious." 35 U.S.C. § 103 (2004). Section 103 denies patents to those devices where "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The "person ... of ordinary skill" is not the inventor but rather someone "who ... is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights ..." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed.Cir.1985). Obviousness must be evaluated not by reference to each individual part claimed, but rather by reference to the invention as a whole. *Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 724 (Fed.Cir.1990). To avoid the temptation of what the Federal Circuit has termed the "hindsight trap," courts require some motivation or teaching that would lead a person of ordinary skill in the art to arrive at the claimed invention. *See In Re Rouffet*, 149 F.3d 1350 (Fed.Cir.1998).

An assessment of the likelihood of validity of a patent claim over the prior art involves a two-step process similar to that used for assessing the likelihood of success on the merits. *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1339 (Fed.Cir.2003); *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1353 (Fed.Cir.1999). In the first step, the court must construe the claims asserted. *Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1353 (Fed.Cir.1999). The second step requires the court to compare the asserted claims with the prior art. Whether a claim would have been obvious under 35 U.S.C. § 103 is a ques-

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tion of law based on findings of fact. *Smiths*, 183 F.3d at 1354. When the presumptions and burdens that will inhere at trial are considered, the injunction should not issue if the opposing party raises "a substantial question concerning infringement or validity, meaning that it asserts a defense that [the moving party] cannot prove lacks substantial merit." *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.2d 1357, 1365 (Fed.Cir.2002).

*5 Teva alleges that Abbott's patents in suit are invalid because of obviousness. The party alleging invalidity has the burden of persuasion on demonstrating invalidity. To establish a prima facie case of obviousness, there must be a showing of a teaching in the prior art that would lead one of ordinary skill to combine the relevant teachings of the prior art references. *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1359-60 (Fed.Cir.1999). In a challenge based on obviousness under 35 U.S.C. § 103, the party alleging invalidity must show prior art references which alone or combined with other references would have rendered the invention obvious to one of ordinary skill in the art at the time of invention. The party seeking a finding of patent invalidity based on obviousness must also show some motivation or suggestion to combine the prior art teachings. *See In re Rouffet*, 149 F.3d 1350, 1355 (Fed.Cir.1998); *Motorola Inc. v. Interdigital Technology Corp.*, 121 F.3d 1461, 1472 (Fed.Cir.1997). A suggestion or motivation to combine generally arises in the references themselves, but may also be inferred from the nature of the problem or occasionally from the knowledge of those of ordinary skill in the art. *See Rouffet*, 149 F.3d at 1355.

To determine obviousness, a court examines 1) the scope and content of the prior art; 2) the level of ordinary skill in the art; 3) the difference between the claimed invention and the prior art; and 4) the objective evidence of nonobviousness. *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1320 (Fed.Cir.2004) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966)). The standard for obviousness does not require absolute predictability but rather looks for a "reasonable expectation of success." *See In re O'Farrell*, 853 F.2d 894, 904-904 (Fed.Cir.1988).

a. *Claims 2 and 4 of the '718 patent*

Claim 2 of the '718 patent [FN2] describes "the pharmaceutical compound of claim 1 ["A pharmaceutical composition for extended release of an erythromycin derivative in the gastrointestinal environment, comprising an erythromycin derivative and from about 5 to about 50% by weight of a pharmaceutically acceptable polymer, so that when ingested orally, the composition induces statistically significantly lower mean fluctuation index in the plasma than an immediate release composition of the erythromycin derivative while maintaining bioavailability substantially equivalent to that of the immediate release composition of the erythromycin derivative"], wherein the polymer is a hydrophilic water-soluble polymer." U.S. Pat. No. 6,010,718, at 11:39-40. Put in simpler terms, the claim describes a composition of "an erythromycin derivative" combined with a hydrophilic water-soluble pharmaceutically acceptable polymer to make an extended release formulation.

FN2. Abbott filed its application for the '718 patent on April 11, 1997; the patent was issued on June 4, 2000.

Claim 4 repeats the description of the pharmaceutical composition from claim 1 and adds that "upon oral ingestion, maximum peak concentrations of the erythromycin derivative are lower than those produced by an immediate release pharmaceutical composition, and area under the concentration-time curve and the minimum plasma concentration are substantially equivalent to that of the immediate release pharmaceutical composition." U.S. Patent No. 6,010,718, at 11:48-58. This means that the concentration-time curve representing the concentration of drug in blood plasma will be flatter and lower for the extended release formulation than for the immediate release formulation, but will have an area under the curve ("AUC") that is substantially equivalent to that of its immediate release corollary. At the same time, the minimum plasma concentration for the extended release formulation will be substantially the same as that of the immediate release formulation, meaning that the drug will be present in the blood at the same minimum level at all times for both the immediate release and extended release formulations.

*6 The parties do not dispute that clarithromycin is an erythromycin derivative. The extended release composition at is-

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sue is designed for release in the gastrointestinal environment (e.g., oral administration). They agree that both Abbott's and Teva's products contain from about 5 to about 50% of a pharmaceutically acceptable polymer (specifically HPMC).

The language of the '718 patent itself states that the "pharmaceutically active compound" of the composition "is an erythromycin derivative." It goes on, "[p]referably, the erythromycin derivative is 6-O-methoxy erythromycin A, known as clarithromycin." The language of the claim is definite ("is an erythromycin derivative") but not closed. It does not specify that the pharmaceutically active compound "is a member selected from the group consisting of A, B, and C." The patent further defines "erythromycin derivative" as meaning "erythromycin having no substituent groups, or having conventional substituent groups, in organic synthesis, in place of a hydrogen atom of the hydroxy groups and/or a methyl group of the 3'-dimethylamino group, which is prepared according to the conventional manner." U.S. Pat. No. 6,010,718, at 3:34-39. From this language, "erythromycin derivative" includes only two macrolides: erythromycin A and clarithromycin. *See also* Teva's 2d Lee Decl., at ¶ 75.

The '718 patent description of the "pharmaceutically acceptable polymer" uses a closed term. Claim drafters often use the term "group of" to signal a Markush group, which lists specified alternatives in a patent claim. The typical form of a Markush group is "a member selected from the group consisting of A, B, and C." *See Manual of Patent Examining Procedure* § 803.2 (2004) (quoted in *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1372 (Fed.Cir.2005)). By its nature, the Markush group is closed. The '718 patent describes the "pharmaceutically acceptable polymer" as "a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acids copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof." U.S. Pat. No. 6,010,718, at 3:65-4:4. It describe the "more preferabl[e]" polymer as hydroxypropylmethyl cellulose, or HPMC. There is no dispute over whether the claim includes HPMC; clearly, it does. The term excludes other forms of polymers, such as hydrophobic or water insoluble substances (e.g., wax).

Teva notes that Abbott defined "erythromycin derivative" in the '718 patent in such a way as to leave out azithromycin. Azithromycin is the name for 9a-aza-9a-methyl-9-deoxo-9a-homoerythromycin A. Pfizer, the patent holder on azithromycin, describes azithromycin as a "broad spectrum antimicrobial compound derived from erythromycin A." WO 95/30422 (the '422 patent"). It is likely that Abbott consciously defined "erythromycin derivative" as it did to avoid infringing Pfizer's existing '422 patent. Abbott argues and Teva concedes that azithromycin is not identical to clarithromycin. The questions are: how similar and dissimilar are the two molecules; and what are the implications of these similarities and dissimilarities to a person of ordinary skill in the art in light of prior art at the time of the invention. Specifically, would a person of ordinary skill in the art have had a reasonable expectation of success in creating an extended release formulation of clarithromycin using a hydrophilic water-soluble polymer based on the prior art, including the '422 patent for an extended release formulation of azithromycin with such a polymer?

*7 Teva's expert contends that the prior art was sufficient such that it would have been obvious to a person of ordinary skill in the art [FN3] that there was a reasonable expectation of success in making an extended release formulation of clarithromycin with the claimed attributes. From the 1950s onward, Teva asserts, extended release formulations were known to persons skilled in the art. By at least the mid-1960s, persons skilled in the art would have known about the use of HPMC in formulating extended release drugs. The basic patent for this technology, U.S. Patent No. 3,065,143, was granted in 1962, and describes "a dosage unit form for the administration of medicaments which releases the medicament at a relatively uniform rate over a long period of tine." The patent goes on to describe motivations for designing an extended release dosage form, including avoiding gastrointestinal side effects. By the late 1980s, using HPMC to formulate extended release dosage forms of pharmaceuticals was "well within the skill of the art." Teva's 2d Lee Decl., at ¶ 50. In addition, by the early 1990s, leading pharmacokinetics textbooks disclosed the ideal

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pharmacokinetic profile of an extended release dosage form. Specifically, the textbooks taught that the ideal formulation would have a longer time to maximum blood plsama concentration of the drug (Tmax) and lower maximum blood plasma concentration of the drug (Cmax), but maintain substantially the same bioavailability as the corresponding immediate release form. Textbooks also disclosed that the degree of fluctuation of blood plasma drug levels was a useful parameter for evaluating extended release formulations. *Id.* at ¶ 54. By the mid-1980s, extended release formulations were being used to reduce or minimize gastrointestinal side effects associated with fluctuating blood plasma drug levels. 2 Robert S. Langer & Donald L. Wise, *Medical Applications of Controlled Release* 23 (1984). Teva's expert notes that an extended release form of azithromycin, another macrolide, had been developed for the purpose of reducing GI side effects. Teva describes this dosage form as "essentially identical to the dosage form disclosed in the '718 patent." Teva's 2d Lee Decl., at ¶ 58.

> FN3. Teva's expert defined "person of ordinary skill in the art" as someone with either "a Ph.D. in pharmaceutical chemistry or a related field and at least two years experience in formulating drugs" or a skilled artisan with "a Bachelor's or Master's Degree in an appropriate field and substantially more practical experience in formulating drugs." Teva's 2d Lee Decl., at ¶ 45.

Teva argues that by the early 1990s, persons of ordinary skill in the art would have known that erythromycin A, clarithromycin, and azithromycin, all closely related molecules, had similar properties for the purpose of designing dose forms. Clarithromycin and azithromycin, both erythromycin derivatives, were developed by making small changes to the molecular structure of erythromycin. The principal considerations for formulating a drug in a particular dosage form are molecular size, solubility, and compound acidity (or pKa). Erythromycin A, azithromycin, and clarithromycin have similar sizes, solubilities, and pKa values. Teva's 2d Lee Decl., at ¶ 63. In addition, Abbott's U.S. Patent No. 5,705,190 ("the '190 patent"), filed in 1995, disclosed and claimed that the three compounds can be used in similar formulations with similar results. Taisho Pharmaceutical Co., Abbott's licensor for clarithromycin (international patent application WO 93/17667, published in 1993) disclosed dosage forms for improving the taste of "an unpleasantly tasting basic drug," including forms such as erythromycin A, azithromycin, and clarithromycin. Teva purports to set out a series of prior art references that would support a finding of invalidity for obviousness of Abbott's extended release formulation patents. Teva points to two patents issued in the 1980s which disclosed dosage forms for extended release compositions including erythromycin stearate and HPMC. U.S. Patent No. 4,369,172; U.S. Patent No. 4,871,548. During the 1990s, Pfizer's '422 patent application disclosed using hydrophilic polymers, such as HPMC, to make extended release dosage forms of azithromycin to control gastrointestinal side effects.

*8 Teva's expert opines that the subject matter of each of Abbott's claims asserted under the '718 patent would have been obvious. Teva bases this on the prior art, which it argues created a motivation to make an extended release formulation of clarithromycin. The half life of immediate release clarithromycin was between three and seven hours, depending on dosage; thus, patients had to take the drug twice per day, which led to greater blood plasma drug level fluctuations and consequently, greater negative side effects such as gastrointestinal distress and taste perversion. Teva contends that a person of ordinary skill in the art would have known that an extended release formulation would reduce these side effects and that formulations using HPMC had been previously made with clarithromycin's close molecular relatives erythromycin A and azithromycin. Thus, a person of ordinary skill in the art would have had a reasonable expectation of success in making an extended release formulation of clarithromycin using HPMC with the described characteristics. In addition, Teva asserts that claim 2 of the '616 patent is invalid for obviousness because the use of extended release formulations in reducing gastrointestinal side effects of drug was widely known by the mid-1990s. It was also known that the principal side effects of erythromycin and its derivatives, including clarithromycin, are gastrointestinal and that the effects vary with dosage amount.

Abbott notes that most inventions arise from a combination

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of old elements. The Federal Circuit has stated that "identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention." *In re Kotzab*, 217 F.3d 1365, 1370 (Fed.Cir.2000). Instead, "there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant."

Abbott submitted declarations from its own experts.[FN4] According to its expert testimony, Abbott contends that its '718 and '616 patents would not have been obvious. Abbott contends that Teva incorrectly assumes that the active pharmaceutical compound in a formulation is interchangeable. Instead, Abbott contends that even similar molecular compounds such as the erythromycin derivatives azithromycin and clarithromycin are too different to be exchanged in such a manner. As an initial question, drug formulators seeking to create an extended release formulation closely consider such parameters as metabolism and excretion characteristics of a drug. Drugs with very short or very long half lives are often unsuited for extended release formulations. Azithromycin has a half-life of almost 70 hours, compared to clarithromycin's half life of three to four hours. Abbott notes that although Pfizer patented an extended release formulation of azithromycin (the '422 patent), it has apparently never attempted to commercially exploit the product. Banker Supp. Decl., at ¶ 31. Azithromycin and clarithromycin are also metabolized very differently by the human body. Clarithromycin produces an active metabolite, whereas azithromycin does not. Banker Supp. Decl. at ¶ 29. Azithromycin can be taken with or without food, but extended release clarithromycin must be taken with food (the "food effect") in order to maintain substantially the same bioavailability as the immediate release version. *Id.* at ¶ 33. The chemical structure of the molecules differs as well. Azithromycin has a 15-member ring structure with a nitrogen atom in the 10-position, which makes it somewhat more stable in the gastric environment than clarithromycin, a macrolide without such a structure. *Id.* at ¶ 34. Thus, Abbott argues, a person of ordinary skill in the art would not have had a reasonable expectation that the azithromycin formulation disclosed in the '422 patent was applicable to clarithromycin or would lead to the features claimed in the '718 patent.

FN4. Abbott's expert, Gilbert Banker, described the person of ordinary skill in the art differently from Teva's expert. According to Abbott, "the typical person working to develop formulations such as those claimed in the patents in suit would have an undergraduate degree in a relevant field of study, such as pharmacy, chemistry, or chemical engineering, plus about two years of experience in the field of formulation." Banker Supp. Decl., at ¶ 12. This court finds Teva's characterization more persuasive, as it is based on more extensive and more direct industry experience.

***9** In addition, Abbott notes that the polymer selected for the invention was not obvious. There were other polymers available. Indeed, Abbott had patented another form, alginate, and conducted several years of research on extended release formulations of clarithromycin with alginate. Teva contends that Abbott's failure with the alginate formulation does not make the use of HPMC any less obvious but rather implies a reluctance to abandon a research avenue. Teva also notes that Abbott held a broad patent on alginate formulations and so had a financial incentive to exploit it. However, Abbott contends that "numerous other extended release [formulation] methods existed at the time of the invention, including osmotic pumps, microspheres, diffusion-controlling films and membranes, and ion exchange technology." Banker Supp. Decl., at ¶ 6.

Teva has provided prior art consisting of textbook excerpts, government publications to the industry, previously issued patents, industry sales brochures, an excerpt from the *Physicians' Desk Reference*, and articles from trade journals. A review of these materials demonstrates that there were sources in the prior art discussing extended release formulations and seeking ways to develop formulations that achieved desirable pharmacokinetic goals. The key difference between the prior art and the claims at issue in the '718 patent is that none of the prior art specifically discloses the combination of an erythromycin derivative with a water soluble hydrophilic polymer to achieve the asserted claims. The question is whether combining clarithromycin with the prior art references, with a reasonable expectation of achieving the asserted claims, would have been obvious to one

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skilled in the art.

Abbott contends that Teva's argument is fatally flawed because it fails to analyze the obviousness of the invention as a whole. Abbott admits that Teva can identify references in the prior art with discrete elements of the invention. However, none of these individual prior art references alone or in combination constitute the invention that is the subject of the '718 patent. Abbott argues that Teva has failed to show the existence of any suggestion or motivation to combine these prior art references or to demonstrate how they would be combined to arrive at the claimed invention.

This court finds that Teva has failed to raise a substantial question as to the validity of Abbott's claims 2 and 4. The prior art cited by Teva discloses discrete portions of the asserted claims, but Teva fails to demonstrate that this would be sufficient to give a person of ordinary skill in the art a reasonable expectation of success. Teva's prior art references reveal that using HPMC was a logical line of inquiry but the dissimilarities between the drugs with which HPMC had been successfully combined and clarithromycin defeat Teva's claim of obviousness. This court is mindful of the Federal Circuit's warning about the risk of the "hindsight trap," or the post facto belief that an invention, which seems obvious once created, would have been obvious to people skilled in the art at the time. Abbott has provided ample evidence that its invention was not obvious and that there were many other extended release formulation methods known in the prior art. In fact, the existence of alternate methods and the attempted exploitation of some of those methods provide secondary considerations of nonobviousness. These factors suggest that there was a long-felt need for the invention, that others, including Abbott, initially failed to develop the invention, and go a long way to account for the commercial success that Abbott has unquestionably enjoyed with its BIAXIN XL product. *See, e.g.*, *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1324 (Fed.Cir.2004); *see also For Your Ease Only, Inc. v. Natural Sci. Indus., Ltd.*, No. 02-C-1584, 2003 WL 22112997, at *7-*9 (N.D.Ill., Sept.10, 2003).

b. *Claim 6 of the '718 patent*

***10** Claim 6 is defined as "an extended release pharmaceutical compound comprising an erythromycin derivative and a pharmaceutically acceptable polymer, the composition having an improved taste profile as compared to the immediate release formulation." U.S. Pat. No. 6,010,718, at 12:23-27. The terms of the patent do not explicitly define "taste profile." Rather, they define "taste perversion" as "the perception of a bitter metallic taste normally associated with the erythromycin derivatives, particularly, with clarithromycin." U.S. Pat. No. 6,010,718, at 3:53-55. In the description of Example 3, the words "taste profile" appear in parentheses immediately following the words "taste perversion." *Id.* at 9:23-24. A reasonable inference is that the terms are used synonymously.

Teva contends that claim 6 should be found invalid for obviousness. It was known that clarithromycin caused taste perversion and this created a motivation for formulators to try to create an extended release formulation that would have a improved taste profile. As support, Teva cites a 1993 article written by Abbott researchers, discussing the pharamacokinetics of single- and multiple-dose clarithromycin. S.-y. Chu et al., *Single- and Multiple-dose Pharmacokinetics of Clarithromycin, a New Macrolide Antimicrobial*, 33 J. Clin. Phamacol. 719-26 (1993). The article disclosed a study performed on thirty-eight human subjects, of whom one reported taste perversion as a side effect at the 500 milligram dose level. One subject also reported incidences of hot flashes and another reported nausea at that dosage level. *Id.* at 721. This study and its publication in an industry journal demonstrate that an invention that would reduce taste perversion would have been obvious to a person of ordinary skill in the art at the time, according to Teva.

Abbott notes that Teva provides evidence only with reference to "taste masking," and not to "taste perversion." Taste masking, somewhat inscrutably, is "a process that prevents the dosage from dissolving in the mouth." Banker Supp. Decl., at ¶ 37 n. 6. Taste perversion, by contrast, continues while the drug is present in the bloodstream and commonly results in a chronic unpleasant metallic taste. In addition, Abbott argues that Teva's reliance on the Abbott study disclosed in the *Journal of Clinical Pharmacology* overstates its case. Only one of thirty-eight subjects reported taste perversion as a side effect, and only at one of four different

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dosage levels. Teva's additional reliance on Pfizer's '422 patent is inapposite, according to Abbott, because nothing in the '422 patent discusses either taste masking or taste perversion at all. Banker Supp. Decl., at ¶ 39. Abbott asserts, moreover, that the mere fact of taste perversion does not make the '718 patent, specifically claim six, obvious. It also states that Teva has not shown evidence that taste perversion is, in fact, dose dependent. Abbott's expert testified that taste perversion is a poorly understood physiological phenomenon and that even if it is dose dependent, it does not logically follow that an extended release formulation would reduce the phenomenon. Banker Supp. Decl., at ¶ 41. Abbott contends Teva has offered insufficient evidence to support a finding of obviousness.

***11** This court agrees with Abbott that Teva has not met its burden of raising a substantial question as to the validity of claim 6. Teva relies primarily on only one study, cited apparently in only one article, that mentions taste perversion as a known side effect of clarithromycin, and even then, in only one of thirty-eight research subjects. This court finds that Teva has failed to provide sufficient evidence to demonstrate that improved taste profile as a result of an extended release formulation of clarithromycin would have been obvious to an ordinary person skilled in the art.

c. *Claim 2 of the '616 patent*

Claim 2 of the '616 patent [FN5] describes "a method of reducing gastrointestinal adverse side effects comprising administering an effective amount of an extended release pharmaceutical composition comprising an erythromycin derivative and a pharmaceutically acceptable polymer, wherein the erythromycin derivative is clarithromycin." U.S. Patent No. 6,551,616, at 12:39-46.

> FN5. Abbott filed its application, which subsequently matured into the '616 patent, on October 13, 1999; the patent was issued on April 22, 2003.

Teva asserts that claim 2 of the '616 patent should be found invalid because it claims an obvious method. Well before the invention of the patent, adverse gastrointestinal effects were widely known as side effects of both erythromycin and clarithromycin and, to a lesser degree, azithromycin. In addition, persons skilled in the art knew that one way to reduce these gastrointestinal effects was to formulate the drug in a polymer matrix, e.g., an extended release formulation. Teva's 2d Lee Decl., ¶ 56. The GI side effects of clarithromycin were known to be dependent on the drug concentration in the blood. Moreover, the '422 patent for extended release azithromycin disclosed that extended release compositions of that closely-related compound reduced gastrointestinal side effects. Thus, "the '616 patent represents nothing more than the routine application of routine skill." Def.'s Opp. Br. at 8.

With respect to claim 2 of the '616 patent, Abbott contends that the gastrointestinal side effects of different active pharmaceutical agents are so distinct that the pharmacokinetic properties of a formulation with one drug are not predictive of a similar formulation with another drug. Abbott concedes, however, that it was generally known in the prior art that an extended release formulation could cause a reduction in adverse gastrointestinal side effects. Abbott disagrees that this "general knowledge" would support "a reasonable expectation that such an effect could even be achieved." Banker Supp. Decl., at ¶ 46. Specifically, Abbott contends that simply knowing that an extended release formulation would reduce the maximum blood plasma concentration of the drug (Cmax) and that such a reduction might lead to reduced GI side effects, one would not know by how much to lower the Cmax in order to reduce the GI side effects. *Id.* at ¶ 47. Therefore, claim 2 of the '616 patent was not obvious but represents a genuine invention.

This court finds that Teva has raised substantial question about the validity of the '616 patent and that Abbott has failed to meet its burden of demonstrating that Teva's opposition lacks substantial merit. This court finds that the prior art, specifically the discussions in industry treatises and medical journals of formulations that reduced GI irritation, the teachings of the '422 patent, and the reference material in the *Physicians' Desk Reference* regarding side effects, would lead a person of ordinary skill in the art to expect that an extended release formulation of clarithromycin would reduce adverse GI side effects.

d. The '386 patent

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***12** Teva argues that the '386 patent is invalid for two distinct reasons. First, Teva asserts that erythromycin A 9-oxime had been disclosed (prior to the '386 patent) in the '014 and '185 patents as both an antibiotic by itself and as a useful intermediate in the synthesis of other products. Teva posits that clarithromycin and erythromycin A are structurally very similar (differing only by the presence of a single "methyl" group) and that they are both broad spectrum antibiotics. Therefore, Teva concludes, a person skilled in the art would have recognized that clarithromycin 9-oxime would likely be an active antibiotic on its own, and would also be an intermediate in the synthesis of other compounds. As the discussion, *supra*, of the '718 patent reveals, erythromycin A, clarithromycin, and azithromycin, while closely related molecules, have some very different, in addition to some very similar, characteristics.

The characteristic of 9-oxime as an effective antibiotic appears to be a constant in the process. Moreover, Abbott has not demonstrated that there is anything disclosed in the '386 patent that, given the known utility of 9-oxime as a facilitator in the synthesis of other products, would have made the teaching of that patent nonobvious. Abbott's expert, Stephen Martin, examined the '803 patent (prior art) and concluded that it taught three things about the superiority of clarithromycin over erythromycin A. Clarithromycin had: 1) increased stability in acid; 2) better *in vitro* antibacterial activity; and 3) remarkable *in vivo* activity. The '014 patent (prior art) taught that erythromycin A 9-oxime had three beneficial properties: 1) increased acid stability over erythromycin A; 2) usefulness as an intermediate in the preparation of new compounds with "antibacterial activity" and 3) antibiotic activity.

Dr. Martin concludes that "[w]hile the '014 patent teaches that erythromycin A 9-oxime retains its antibiotic activity, it does not disclose whether it has *in vivo* antibacterial activity." From that conclusion, he goes on to opine that one skilled in the art would have appreciated only that erythromycin A 9-oxime exhibited *in vitro* antibacterial activity and would not have concluded that erythromycin A 9-oxime could be used as an intermediate in the production of other compounds with *in vivo* antibacterial activity. The court does not agree. While there may be persons who care deeply about destroying infectious bacteria in Petrie dishes, this court will assume that persons skilled in the art would be motivated to use the teachings of prior art for their *in vivo* applications. Unless the person skilled in the art was wearing blinders, he or she would have recognized some relationship between *in vitro* and *in vivo* antibacterial agents. The relationship may not have been one-to-one, but the teaching would have suggested a relationship. The standard for obviousness does not require absolute predictability, but rather looks for a reasonable expectation of success. Even without hindsight, a person skilled in the art would have anticipated the *in vivo* usefulness of clarithromycin 9-oxime in light of the *in vitro* benefits of erythromycin A 9-oxime. Therefore, in light of the obviousness of the invention, Abbott has not demonstrated a likelihood of success as to the '386 patent.

B. Irreparable Harm

***13** The party seeking the preliminary injunction must not only show a likelihood of success on the merits but also that it will suffer irreparable harm in the absence of an injunction. The court now turns to this analysis.

If the movant can establish a clear showing of the validity of the patents in suit and infringement thereof, then a presumption of irreparable harm attaches. The burden then shifts to the non-movant to rebut the presumption. *Amazon.com v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed.Cir.2001). A successful rebuttal is a showing that the non-movant either has or shortly will cease its allegedly infringing activities; that the movant has a pattern of granting licenses for the patents in suit so that it is reasonable to believe money damages would be enough to satisfy any harm to the patentee; or that the movant unduly delayed in bringing suit on its patents. *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 974 (Fed.Cir.1996).

As a threshold matter, Abbott is entitled to a presumption of irreparable harm regarding only those patents for which this court has found that it made a clear showing of both infringement and validity. Teva, therefore, bears the burden of rebutting that presumption. To the extent that this court has found that Abbott has not made a clear showing that it will succeed on both infringement and validity, Abbott bears the

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burden of demonstrating that it will suffer irreparable harm in the absence of the presumption.

Abbott contends it has demonstrated irreparable harm because it has shown that it will suffer loss of market share, goodwill, and profits; will be constrained to lay off several hundred sales representatives; and will face losses that will never be fully compensable in money damages. Abbott argues that Teva's assertion that it has sufficient funds to answer for Abbott's future harm is insufficient to rebut the presumption of irreparable injury. *Polymer Techs.*, 103 F.3d at 975. In addition, Abbott offers again a declaration from its BIAXIN brand manager. This declaration describes a financial model that predicts that generic entry would "crush" the market for Abbott's branded extended release clarithromycin. *See* Pl.'s Reply Br. at 13 n. 11. Abbott cites *Hybritech Inc. v. Abbott Laboratories*, 849 F.2d 1446 (Fed.Cir.1988), which stated that "the nature of the patent grant weighs against holding that monetary damages will suffice to make the patentee whole." *Id.* at 1457; *see also Pretty Punch Shoppettes, Inc. v. Hauk*, 844 F.2d 782 (Fed.Cir.1988) ("A money award is not the sole remedy for future infringement of a patent."). The Federal Circuit has stated that evidence on likelihood of price erosion and loss of market position resulting from competitor's entry in a pharmaceutical patent infringement case may support a finding of irreparable harm. *See Purdue Pharma L.P. v. Boehringer Ingelheim, GMBH*, 237 F.3d 1359, 1368 (Fed.Cir.2001) (noting that patentee was entitled to presumption of irreparable harm but analyzing sufficiency of patentee's proferred expert evidence). According to Abbott's brand manager, after two months of generic competition, Abbott will face a 75% decline in market share. Considering competition from the generic immediate release formulations that entered the market on May 24, 2005, Abbott predicts it will lose approximately sixty percent of its market share in the first two months of generic extended release competition. Abbott reiterates the irreversible market share losses it will face as it loses its preferred position on pharmacy and insurance formularies.[FN6] Finally, Abbott notes that although Teva criticizes Abbott's financial model as unduly speculative, Teva provides no alternate model or estimate of Abbott's future losses.

FN6. These arguments were discussed in some detail in this Court's memorandum opinion and order in this case of May 20, 2005, and the Court refers the parties thereto.

***14** Teva asserts that Abbott has failed to establish irreparable harm. It characterizes Abbott's case as "an assertion that it will lose money in the event of competition." Def.'s Opp. Br. at 11. Teva contends that Abbott's financial model is "entirely speculative" and biased because Abbott's own BIAXIN brand manager generated it. Further, Teva criticizes Abbott's estimate of market erosion due to generic immediate release clarithromycin. The model predicts a nearly instant fifteen percent erosion that then continues at that constant rate indefinitely. Teva contends that previous cases where generic immediate release formulations competed against branded extended release formulations demonstrate that this model is inaccurate. *See, e.g.*, 2d Scott-Morton Decl., at ¶ 41. Teva asserts that the market erosion due to the generic immediate release will be much greater than fifteen percent, although Teva provides no estimate of just how great it might be. In addition, Teva notes that Abbott's estimates of the remaining profitability of BIAXIN XL suggest that it would generate ample revenue to fund a marketing and publicity drive designed to return the product to the preferred tier on managed care and Medicaid formularies. Such an effort would help restore much, if not all, of Abbott's market share in the event that a generic competitor entered and subsequently exited the market. Teva has not offered an estimate of how much such a marketing effort would cost, especially given the complexity of the market and the impact of the entry of generic immediate release clarithromycin formulations.

This court finds that Abbott has made a showing that it will suffer irreparable harm with respect to the '718 patent in the absence of a preliminary injunction. In so finding, however, the court reiterates that the parties' models of how the market will react to generic competition for extended release clarithromycin remain highly speculative. As noted in its May 20, 2005 order, this is in large part due to the entry of generic immediate release formulations on May 24, 2005. There is insufficient data to determine whether and the degree to which the generic immediate release product erodes

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the market for extended release clarithromycin. However, the very fact of this instant proceeding strongly suggests that the parties perceive a robust market remaining for the extended release formulation, even with generic competition on the immediate release level. Thus, as previously noted, this court concludes that entry of a generic extended release formulation competitor will likely crush the market.

With respect to the '386 patent, specifically, even if Abbott had successfully met the likelihood of success burden, the motion for a preliminary injunction would be denied because Abbott cannot establish irreparable harm for infringement. Abbott has not suffered and could not prove monetary damages even if the '386 patent had been infringed. As Judge Posner noted, "[d]amages is the amount of loss to a patentee." *Smithkline Beecham Corp. v. Apotex Corp.*, 247 F.Supp.2d 1011, 1046 (N.D.Ill.2003) (citing *Smithkline Diagnostics, Inc. v. Helena Laboratories Corp.*, 926 F.2d 1161, 1164 (Fed.Cir.1991)) In the trace amounts in which 9-oxime appears in the Teva product, Teva derives no competitive advantage and Abbott suffers no competitive disadvantage. As this court noted in its opinion on the TRO, the '386 patent is not a process patent and the presence of 9-oxime in the Teva product is, at best, a fingerprint of a process. Abbott does not claim (and given the minute quantities involved, could not claim) that 9-oxime is used in the Teva product for its antibacterial characteristics. If Teva used exactly the same process to produce its product but removed all of the 9-oxime, Abbott could not assert that any of its patents would be infringed. More importantly, Abbott has not established that it will suffer any loss as a result of infringement of the '386 patent but instead must rely on the presumption that follows from a finding of infringement. Because this Court concludes, preliminarily, that the '386 patent is invalid, the presumption does not arise. If Abbott should prevail on its infringement claim at trial, we will revisit the question of damages (if any).

C. Balance of Hardships

***15** The third factor in determining whether a preliminary injunction should issue requires the court to examine the balance of the hardships between the two parties. *Hybritech*, 849 F.2d at 1457. The court weighs the hardship to the patentee if no injunction is entered against the harm to the alleged infringer if the injunction is granted incorrectly. *Id.*

The structure of the pharmaceutical market makes it difficult to determine the effect of generic competitor market entry. Most prescription drug purchases in the United States are paid for, at least in part, by employer-sponsored health insurance plans or by government programs like Medicaid. When a pharmaceutical enters the market, insurance companies, managed care organizations, and Medicaid plans decide whether to place the drug on their pharmaceutical formularies. The formulary is a list of approved medications for which the plan will pay some part of the cost. These formularies are, in many instances, divided into three tiers. The first tier comprises low cost generic products. The second tier comprises "preferred branded" products. The third tier comprises "non-preferred branded" products. Patients must pay more out-of-pocket for drugs listed on a higher tier than for a drug of the same price listed on a lower tier. The managed care provider typically pays more for drugs listed on a lower tier (e.g., Tier 1) than for a drug of the same price listed on a higher tier (e.g., Tier 3). The Medicaid formulary does not have tiers; either a drug is listed on the formulary (also known as the preferred drug list) or it is not. If the drug is not on the Medicaid formulary, the program will not cover any portion of its cost. If a doctor prescribes a non-formulary drug to a Medicaid patient, the patient must pay the entire cost out-of-pocket.

When a generic version of a branded product enters the market, managed care providers generally add the generic to their formulary on Tier 1. They will then move the branded product to a higher position (e.g., from Tier 2 to Tier 3). Some plans will remove the branded drug from their formulary altogether. If the generic product is AB rated, meaning that the FDA considers it therapeutically equivalent to the branded product, many pharmacies will substitute the generic product for the branded product unless the physician specifies on the prescription form "Dispense as Written." Medicaid programs typically remove branded products from their formularies altogether once a generic has entered the market.

Abbott argues that the balance of hardships weighs in favor of granting the preliminary injunction because it will face devastating loss of market share. Abbott predicts that it will

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lose 40 percent of its sales of BIAXIN XL within one month of generic entry, 64 percent within two months, and 78 percent after eleven months. In addition, it estimates it will suffer approximately $1.37 billion in lost profits (discounted to present value) over the remaining twelve years of its patents; will be constrained to lay off several hundred members of its sales force; and will lose a significant portion of the market for a product which it asserts represents six percent of its annual domestic sales. Moreover, Abbott contends that its loss of market share will be permanent. Once a managed care organization moves a drug to a higher tier on its formulary or, in the case of Medicaid, removes the drug entirely, it is costly and difficult to regain a preferred position. Abbott contends that it will be unable to regain its position on the second tier of most managed care organization formularies and will be unable to be relisted on the Medicaid formulary. Competition from related antibiotics, the financial incentive to the prescription benefit providers of keeping a drug on a higher tier, and simple inertia on the part of the formulary administrators will combine to prevent Abbott from regaining more than a fraction of its current market share, even if a generic competitor subsequently exits the market.

*16 Teva argues that the balance of hardships does not tip in favor of Abbott. It contends that BIAXIN XL represents only 1.5 percent of Abbott's annual sales of approximately $20 billion,[FN7] and that lost sales would not represent a hardship. In addition, it asserts that Abbott will be able to regain all or almost all of its market share through a marketing drive. Because Abbott has spent only $250 million on the production and marketing of its BIAXIN portfolio of products to date, Teva contends that the expense of a campaign to get BIAXIN XL returned to its preferred formulary position represents only a minimal hardship. Teva has not stated what its estimate of potential sales of its generic extended release clarithromycin will be, nor how much it has invested in development, production, and marketing to date. Instead, it contends that such a figure will depend on how many other generic competitors enter the market for extended release clarithromycin and when, and what the state of the market is at the time this case is decided. Although these are real considerations, this court is perplexed by Teva's reluctance or inability to quantify the hardship, if any, it will face if an injunction is incorrectly entered. As a result, this court is left to balance the hardships without information about one half of the balance. In such a situation, there is little choice but to conclude that the balance of the hardships favors the patentee.

FN7. The discrepancy between these sales percentages may be resolved by looking at whether the calculation is based on total sales or domestic sales. The parties did not resolve this issue at the hearing.

D. Public Interest

The final factor a court should consider in determining whether to issue a preliminary injunction is the impact it will have on the public interest. *Hybritech*, 849 F.2d at 1458. "[I]n a patent infringement case, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." *Id.*

Abbott states that granting the preliminary injunction will serve the public interest by furthering the important public policy of encouraging innovation in pharmaceutical development. It emphasizes the value of the right to exclude inherent in a patent. *See, e.g., Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.3d 1573, 1578 (Fed.Cir.1983). Abbott states that it invests approximately nine percent of its annual net sales revenue in research and development.[FN8] The company has invested over $250 million to research, produce, and market its BIAXIN and BIAXIN XL products. McKercher Decl., at ¶ 7. If it cannot reap the full benefit of the twenty-year monopoly conferred by its patent, it argues that its incentive to invest such large amounts in a product would diminish because of the lower expected return from R & D investments. Abbott suggests that it "might well choose instead to divert its resources to other efforts such as advertising, increased customer service, or the like." Pl.'s Br. at 15 (quotations omitted). Thus, the public's "strong interest in creating adequate incentives to innovate" outweighs its interest in allowing generic competition before patent expiration.

FN8. In 2003, Abbott's R & D expenditures were approximately $1.6 billion. Pl.'s Br. at 15

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*17 Teva contends that the public interest is served by permitting competition and allowing companies offering low cost generic products to enter the market and ease the public's burden of high prescription drug costs. In addition, Teva argues that the public interest is not served by the enforcement of allegedly invalid patents or the extension of monopoly pricing by means of invalid patents over the distribution of low cost pharmaceuticals. Teva does, however, admit that there is a public interest in the enforcement of valid patents.

The court recognizes the public interest in competition in the pharmaceutical market. It also recognizes, however, the public interest in creating beneficial and useful products and the cost involved in that process. To the extent that this court has found that the patents in suit are valid, the public interest is best served by enforcing them.

Conclusion

For the foregoing reasons, this court preliminarily finds the '386 patent and claim 2 of the '616 patent invalid for obviousness. The court finds that Teva has not established that claims 2, 4, and 6 of the '718 patent are invalid for obviousness. The court grants Abbott's motion for a preliminary injunction against Teva.

N.D.Ill.,2005.
Abbott Laboratories v. Andrx Pharmaceuticals, Inc.
Not Reported in F.Supp.2d, 2005 WL 1323435 (N.D.Ill.)

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EXHIBIT D

Briefs and Other Related Documents
Only the Westlaw citation is currently available.

United States District Court,D. Delaware.
MERCK & CO., INC., Plaintiff,
v.
WATSON LABORATORIES, INC., Defendant.
No. C.A. 05-658(GMS).

June 2, 2006.

Mary B. Graham, James Walter Parrett, Jr., Morris, Nichols, Arsht & Tunnell, Wilmington, DE, for Plaintiff.
Adam L. Balick, Joanne Ceballos, Bifferato, Gentilotti, Biden & Balick, Wilmington, DE, for Defendant.

MEMORANDUM

GREGORY M. SLEET, District Judge.

*1 In the above-captioned action for patent infringement, plaintiff Merck & Co., Inc. ("Merck") accuses defendant Watson Laboratories, Inc. ("Watson") of infringing several patents by filing Abbreviated New Drug Application ("ANDA") No. 76-768, which is directed to a generic version of one of Merck's brand-name drugs. For reasons that are not important here, Merck decided it does not wish to continue prosecuting this action. Thus, Merck gave Watson a covenant not to sue in which "Merck unconditionally represents, stipulates, agrees, and covenants that it will not sue Watson for infringement of, or otherwise assert, enforce, or hold Watson liable for infringement of [the patents in suit] based on the importation, manufacture, use, sale, or offer for sale of the ... tablets that are the subject of and described in Watson's ANDA No. 76-768...." (D.I. 17, Ex. B at 2.) Presently before the court is Merck's motion to dismiss with prejudice for lack of subject matter jurisdiction.

In *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, the plaintiff in a patent infringement action decided it did not wish to continue prosecuting its claims against the defendant. 57 F.3d 1054, 1056 (Fed.Cir.1995). Although the plaintiff did not take the step of delivering a separately-executed covenant to the defendant, the plaintiff did state in its briefing to the district court that it would "unconditionally agree not to sue [the defendant] for infringement as to any claim of the patents-in-suit based upon the products currently manufactured and sold by [the defendant]." *Id.* Based on this representation, the district court dismissed the case for lack of subject matter jurisdiction. *Id.* at 1057. On appeal, the defendant argued that the plaintiff's promise was legally powerless because it was merely a promise made by counsel in the course of briefing that would be unenforceable against the plaintiff in a future action. *Id.* at 1059. The Federal Circuit disagreed, holding that the counsel's unconditional promise on behalf of the plaintiff was sufficient to bind the plaintiff "both now and in the future, by its promise not to sue [the defendant]," and thereby eliminated any "reasonable apprehension" the defendant may have had of facing an infringement suit. *Id.* As such, the district court had correctly determined that subject matter jurisdiction was lacking. *Id.* at 1060.

In this case, Watson argues that the covenant was "void upon execution" because, although Merck unconditionally promised not to sue Watson, Merck continued to assert its infringement claims against Watson. Thus, according to Watson, Merck's promise not to sue does not remove any "reasonable apprehension" of an infringement suit so long as this suit remains pending. Suffice it to say, Watson's argument is completely at odds with *Super Sack*. There, as here, the suit was still pending when the plaintiff promised not to sue the defendant, and yet the court held that the promise was sufficient to remove any "reasonable apprehension" of an infringement suit. Watson further argues that Merck's covenant is unenforceable due to a lack of consideration. However, as far as the court is able to discern, the promise upheld in *Super Sack* was similarly unaccompanied by consideration. Watson also contends-somewhat confusingly-that because the covenant does not provide for dismissal of the complaint, this court has no jurisdiction to enforce the covenant. Again, the promise by the plaintiff in *Super Sack* seems to have suffered from the same alleged infirmity, and yet it was upheld. Moreover, because any dismissal pursuant to Merck's covenant would be with prejudice, *res judicata* will likely prevent Merck from re-filing this suit regardless of the enforceability of the covenant. Therefore, the covenant is sufficient to remove any "reasonable apprehension" Watson may have of being sued for infringement by Merck.[FN1]

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> FN1. Watson contends that the covenant does not eliminate its apprehension because the covenant is only directed toward the "importation, manufacture, use, sale or offer for sale" of the tablets described in ANDA No. 76-768, but not the infringing act of filing the ANDA in the first place. (D.I. 22 at 9.) However, in its reply brief, Merck concedes that its covenant would indeed prevent it from accusing Watson of infringement by filing the ANDA. (D.I. 23 at 6 n. 1.)

*2 Watson argues that even if the covenant is sufficient, the court retains jurisdiction to resolve the parties' dispute over the form of dismissal because this case involves the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, "which were enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282." *Minn. Mining and Mfg. Co. v. Riker Labs., Inc.*, 289 F.3d 775, 776-77 (Fed.Cir.2002) *("3M")*. In *3M*, the plaintiff argued that the district court lacked subject matter jurisdiction to hear the plaintiff's patent infringement claims because information previously withheld and later disclosed by the defendant revealed that no infringement had actually occurred, thereby eliminating the existence of a case or controversy. *Id.* at 780. Moreover, because the defendant had withheld the exculpatory information, the plaintiff argued that there never was a case or controversy, and therefore, the case should be dismissed without prejudice. *Id.* The defendant disagreed, and argued that the case should be dismissed with prejudice. *Id.* The district court sided with the defendant, and the plaintiff appealed. *Id.* at 779. After explaining that the form of dismissal may have a significant effect on subsequent FDA proceedings due to the Hatch-Waxman Amendments, *i.e.*, possibly triggering a 180-day period of market exclusivity for the first ANDA filer, the Federal Circuit held that the district court did in fact have jurisdiction to resolve the parties' dispute over the form of dismissal. *Id.* at 780. The Federal Circuit further held that the district court was correct to dismiss the plaintiff's claims with prejudice. *Id.* at 783-84.

In this case, Merck and Watson have both submitted proposed orders of dismissal. Merck's proposed order would have the court (1) dismiss all claims and counterclaims with prejudice, (2) order Watson to notify Merck of any changes to ANDA No. 76-768, and reserve the rights of the parties to reinstate their claims and counterclaims in the event that Watson acts outside the scope of Merck's covenant, (3) order each party to bear its own fees and costs, and (4) declare that the dismissal of Merck's claims has no bearing on whether Watson infringes Merck's patents, or on whether Merck's patents are valid and enforceable. (D.I.17, Ex. A.) Watson's proposed order, on the other hand, would have the court (1) declare that ANDA No. 76-768 does not infringe any of the patents in suit, (2) reserve for Merck the right to file a later infringement suit "if Watson seeks approval for or sells a drug product other than the one presently described in" ANDA No. 76-768, (3) dismiss all claims (with prejudice) and counterclaims, (4) announce that it (the court) retains jurisdiction to enforce Merck's covenant, and (5) order each party to bear its own fees and costs. (D.I.22, Ex. F.)

*3 Although these very different proposed orders demonstrate sharp differences of opinion between the parties, the court is unable to resolve those differences in this case. The court's jurisdiction over Watson's declaratory judgment counterclaims is dependent upon a "*reasonable* apprehension on the part of the declaratory plaintiff that it will face an infringement suit." *Super Sack*, 57 F.3d at 1058 (quoting *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed.Cir.1993)) (emphasis in original). However, the parties' agreement that Merck's claims should be dismissed with prejudice eliminates any "reasonable apprehension" of an infringement suit against Watson. Thus, the court has no subject matter jurisdiction to declare that ANDA No. 76-768 does not infringe any of the patents in suit. Moreover, given this court's inability and unwillingness to issue advisory opinions, the court cannot declare that the dismissal of Merck's claims has no bearing on whether Watson infringes Merck's patents, or on whether Merck's patents are valid and enforceable. Furthermore, the court cannot reserve the rights of the parties to reinstate their claims at a later date, because such rulings would prematurely resolve potential disputes between these parties, or between future parties to future lawsuits. Thus, the effect of dismissing

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Merck's claims with prejudice must be left for another day. The court also believes it would be imprudent to order Watson to notify Merck of any changes to ANDA No. 76-768. If Watson or any other ANDA filer is required by statute, regulation, or rule to provide such notification, then it should do so. However, this court will not create an additional obligation for Watson when others similarly situated may not be constrained by such an obligation. The court concludes it would be likewise imprudent to announce that it retains jurisdiction to enforce Merck's covenant in the absence of some alleged violation of that covenant.[FN2]

> FN2. Watson argues that the court retains jurisdiction over Watson's demand for attorneys' fees. However, the seriousness with which Watson makes this argument is belied by the fact that Watson's proposed order of dismissal provides that each party should bear its own fees and costs. Moreover, the stated basis for attorneys' fees-in large part, that Merck filed suit on invalid patent claims-is unconvincing because Merck's petition for *writ of certiorari* seeking to overturn invalidation was denied *after* suit was filed. Merck filed its motion to dismiss only four months later. This sequence of events does not, in the court's opinion, warrant the award of attorneys' fees.

Watson's final argument is that permitting Merck to withdraw its claims at this stage would be improperly prejudicial under Fed.R.Civ.P. 41(a)(2) because such a withdrawal would require Watson to wait until both the expiration of Merck's patents and the expiration of the 180-day exclusivity period before marketing its generic.[FN3] Watson's argument is flawed for at least two obvious reasons. First, dismissal of this case is required under Article III of the United States Constitution, which trumps the Federal Rules of Civil Procedure. Second, it is not clear that Watson will be prejudiced because not all of the patent claims asserted by Merck have been invalidated. Thus, even if the case were to proceed, Watson may not succeed in freeing itself from the reach Merck's intellectual property rights. Therefore, this argument does not warrant denying Merck's motion.

> FN3. Watson was not the first ANDA filer.

ORDER

IT IS HEREBY ORDERED THAT:

1. Merck's motion to dismiss (D.I.17) be GRANTED;

2. All claims of Merck's complaint (D.I.1) be DISMISSED with prejudice;

*4 3. All counterclaims of Watson's answer (D.I.5) be DISMISSED for lack of subject matter jurisdiction; and

4. Watson's motion for leave to file a motion for summary judgment (D.I.20) be DENIED.

D.Del.,2006.
Merck & Co., Inc. v. Watson Laboratories, Inc.
Slip Copy, 2006 WL 1537375 (D.Del.)

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- 2006 WL 1199979 (Trial Motion, Memorandum and Affidavit) Plaintiff Merck & Co., Inc.'s Reply Brief in Support of its Motion to Dismiss for Lack of Subject Matter Juridiction in Light of Merck's Covenant not to Sue (Mar. 20, 2006) Original Image of this Document (PDF)
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EXHIBIT E

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Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2005 WL 1705295 (S.D.N.Y.)
(Cite as: Not Reported in F.Supp.2d)

H

Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court,S.D. New York.

EON LABS, INC., Plaintiff,

v.

PFIZER INC., Defendant.

No. 05 CIV 0002LAP.

July 19, 2005.

MEMORANDUM AND ORDER

PRESKA, J.

*1 Plaintiff Eon Labs, Inc., ("Plaintiff") brings the present suit pursuant to 28 U.S.C. § 2201, the Declaratory Judgment Act, against Defendant Pfizer, Inc. ("Defendant"). Defendant presently moves to dismiss Plaintiff's Complaint for lack of subject matter jurisdiction. Because Plaintiff has not established that it is in reasonable apprehension of suit, Defendant's motion is granted.

I. *Background*

Defendant manufactures and markets Zithromax brand azithromycin. Zithromax is covered by several United States patents, including U.S. Patent Nos. 5,605,889 (the " '889 Patent"), and 6,268,489 (the " '489 Patent"). The Patents are set to expire in November 2005. Plaintiff manufacturers and markets generic pharmaceuticals in the United States and has filed three Abbreviated New Drug Applications ("ANDAs") by which it seeks expedited approval to market generic versions of Zithromax brand azithromycin. Plaintiff filed a complaint for declaratory judgment seeking a declaration that Eon's generic version of azithromycin will not infringe upon any claim made by Pfizer on the '889 Patent or the '489 Patent.

Defendant asserts that Plaintiff: (1) has failed to allege an immediate and real controversy; and (2) has no reasonable apprehension of suit alleging copyright infringement against Plaintiff's '889 and '489 Patents. Plaintiff contends that reasonable apprehension of suit does exist, and it relies on: (1) Defendant's history of litigation in defending its patents; (2) Plaintiff's dependence on Teva Pharmaceuticals ("Teva") for its source of azithromycin; and (3) Defendant's refusal to grant a covenant not to sue.

II. *Discussion*

The Declaratory Judgment Act, 28 U.S.C. § 2201(a), provides:

[i]n a case of actual controversy within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

As a threshold matter, the Declaratory Judgment Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed.Cir.1996). The actual controversy requirement is met when, "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issue of a declaratory judgment." *Id.* (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 213 U.S. 270, 273 (1941)). This actual controversy must be in existence at all stages of the litigation and cannot merely be present at the filing of the complaint. *Dr. Reddy v. aaiPharma*, 66 U.S.P.Q.2d 1878, 1884 (2002), (quoting *Super Sack v. Chase* 57 F.3d 1054, 1058 (Fed.Cir.1995)). However, when an actual controversy does exist sufficient to warrant subject matter jurisdiction, "the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction." *EMC Corp.*, 89 F.3d at 810.*2 In the classic patent declaratory judgment suit, *i e*, where the declaratory plaintiff is laboring under the threat of litigation for alleged infringement of a patent, the 'actual controversy' requirement means that there is a jurisdiction over the action if (1) the declaratory plaintiff has acted, or has made preparations to act, in a way that could constitute infringement, and (2) the patentee has created in the declaratory plaintiff a reasonable apprehension that the patentee will bring suit if the activity in question continues.

Fina Oil v. John Ewen, 123 F.3d 1466, 1470 (Fed.Cir.1997)

The first element of this test is satisfied if the declaratory

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plaintiff takes "concrete steps" towards activity that would constitute infringement. *Kos Pharmaceuticals, Inc. v. Barr Laboratories, Inc.* 242 F.Supp.2d 311, 317 (S.D.N.Y.2003). Here, the parties agree that the filing of an ANDA constitutes concrete steps towards infringement. "35 U.S.C.S. § 271(e)(2) provides that a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent." *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1328 (Fed.Cir.2005).

The second element of the test is satisfied if the defendant has engaged in conduct that creates on the part of the declaratory plaintiff a reasonable apprehension of suit. *Jervis B. Webb Co. v. Southern Systems, Inc.*, 742 F.2d 1388, 1398 (Fed.Cir.1984). This apprehension does not have to be the result of an express charge of infringement. "[T]he apprehension may be induced by subtler conduct if that conduct rises 'to a level sufficient to indicate an intent [on the part of the patentee] to enforce its patent,' *i.e.*, to initiate an infringement action." *EMC Corp.*, 89 F.3d at 811 (quoting *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 887 (Fed.Cir.1992)). Without conduct amounting to an express charge of infringement, "the declaratory plaintiff must establish an actual controversy on the 'totality of the circumstances.' " *Dr. Reddy*, 66 U.S.P.Q.2d at 1884, (quoting *Goodyear Tire and Rubber Co. V. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed.Cir.1987)).

Courts have specifically identified certain conduct as contributing to a declaratory plaintiff's reasonable apprehension. "[T]he fact that parties are engaged in litigation at the time the perceived threat is made or the fact that the patent holder has stated an intent to enforce its patent rights," may contribute to a declaratory plaintiff's apprehension. *Dr. Reddy*, 66 U.S.P.Q.2d at 1884. The parties' prior and current litigation may also "demonstrate a significant legal history with respect to the manufacture of generic drugs." *Id.* at 1885. In addition, declaratory plaintiffs may point to the defendant's history of defending their patents and their failure to grant a covenant not to sue. However, "[a]lthough relevant to the analysis, neither of the factors ... is dispositive." *Teva Pharms. USA, Inc.*, 395 F.3d at 1333.

***3** In the present case, Plaintiff asserts the existence of an immediate and real controversy. As a threshold matter, Plaintiff must establish an immediate and real controversy as a necessary step towards showing reasonable apprehension. *See, e.g., id.* In other words, Plaintiff must show that the alleged threat posed by Defendant is imminent. Here, Defendant's basic patent will expire in November 2005, and it takes approximately one month for an ANDA to be approved. *Teva Pharmaceuticals USA, Inc. v Pfizer Inc*, Nos. 03-CV-7423 and 04-CV-4979, slip ops. (S.D.N.Y. July 27, 2004). Courts have routinely recognized imminence in cases where the marketing of generic pharmaceuticals will not take place for approximately two years. *See, e.g., Kos*, 242 F.Supp.2d 311 at 318; *Glaxo v. Apotex*, 130 F.Supp.2d 1006, 1009 (N.D.Ill. 2001). Accordingly, Plaintiff has established the existence of an immediate and real controversy.

Moving to the question of reasonable apprehension of suit, Plaintiff essentially lists three factors as contributing to its reasonable apprehension: (1) Defendant's past litigation behavior with respect to generic drug manufacturers; (2) Plaintiff's special relationship to another plaintiff before this Court in another case, Teva; and (3) Defendant's refusal to grant a covenant not to sue.

In describing Defendant's past litigation behavior, Plaintiff provides a history of infringement suits brought by Defendant against generic competitors, including foreign litigation concerning other patents. Plaintiff also references past patent infringement suits between these parties concerning different technologies. It is undisputed that Defendant has not initiated any proceedings, including foreign litigation, against Plaintiff with respect to the '889 or '489 patents or the technology generally.

While Plaintiff does argue that Defendant has sued Plaintiff in the past with regard to the drug Neurontin (unrelated to Zithromax), the Court of Appeals for the Federal Circuit has disclaimed the existence of reasonable apprehension where the patentee has sued the particular defendant in connection with different technologies. *See Apotex, Inc. v. Pfizer, Inc.*, No.04-CV-2539 (DC), 2005 WL 22849, at *7 (S.D.N.Y. Jan. 3, 2005). And while Defendant clearly has a history of defending its patents, such general history is insufficient to establish reasonable apprehension on the part of this declaratory plaintiff. *See Teva Pharms. USA, Inc.*, 395 F.3d at

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1333. Reasonable apprehension must be proved by objective evidence of the conduct of the patentee. "A purely subjective apprehension of an infringement suit is insufficient to satisfy the actual controversy requirement." *Indium Corp. of Am. v. Semi Alloys, Inc.*, 781 F.2d 879, 883 (Fed.Cir.1985).

Second, Plaintiff argues that the special relationship between itself and Teva, Inc. contributes to its reasonable apprehension of suit. Plaintiff relies upon this Court's reasoning in *Teva Pharms. USA, Inc. v. Pfizer, Inc.* (the "Teva Case") to conclude that the business relationship between Plaintiff and Teva (Plaintiff states that it is dependent upon Teva for its azithromycin and has identified Teva as its source of azithromycin in its ANDAs) confers upon the Plaintiff the same standing as Teva. However, Plaintiff provides no case law to support this novel contention. Absent such legal support, this Court can only accord the Teva Case the same precedential value it would any other relevant patent infringement case.

*4 The Teva Case is also readily distinguishable from the present case. There, Pfizer had sued Teva for patent infringement in a foreign jurisdiction prior to Teva's declaratory judgment action; no such litigation history exists here. Defendant can only reference one past lawsuit where Defendant sued Plaintiff for patent infringement with regard to a different technology. A single lawsuit with respect to different technology does not create a history of litigation that can objectively give rise to reasonable apprehension. *Teva Pharms. USA, Inc.*, 395 F.3d at 1333.

Finally, Plaintiff argues that Defendant's refusal to grant a covenant not to sue is further evidence of their reasonable apprehension. Notwithstanding the fact that Plaintiff's request for a covenant not to sue from Defendant was made two weeks *after* the filing of the Complaint, "a refusal to grant a covenant not to sue ... [a]lthough relevant to the analysis ... is not dispositive." *Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1324, 1333 (Fed.Cir.2005). In *Teva Pharmaceuticals USA, Inc.*, the Court of Appeals for the Federal Circuit ruled that although Defendant Pfizer: (1) had a history of defending its intellectual property against Plaintiff Teva; (2) had refused to grant a covenant not to sue; and (3) had initiated previous lawsuits against a competitor of Plaintiff Teva concerning the same technology, no reasonable apprehension existed. Here, Plaintiff can only duplicate one of the three factors-the refusal to grant a covenant not to sue-that the Court of Appeals has already deemed insufficient to establish reasonable apprehension of suit.

III. *Conclusion*

Accordingly, Defendant's motion to dismiss (Docket No. 13) is granted as Plaintiff has failed to establish any reasonable apprehension of suit. The Clerk of the Court shall mark this action closed and all pending motion denied as moot.

SO ORDERED

S.D.N.Y.,2005.
Eon Labs, Inc. v. Pfizer, Inc.
Not Reported in F.Supp.2d, 2005 WL 1705295 (S.D.N.Y.)

Briefs and Other Related Documents (Back to top)

- 2005 WL 3338042 (Trial Motion, Memorandum and Affidavit) Defendant's Memorandum in Support of its Motion to Dismiss the Complaint for Lack of Subject Matter Jurisdiction (Feb. 23, 2005) Original Image of this Document (PDF)
- 1:05cv00002 (Docket) (Jan. 03, 2005)
- 2004 WL 3611839 (Trial Pleading) Complaint for Declaratory Judgment (Dec. 30, 2004) Original Image of this Document (PDF)

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EXHIBIT F

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Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court,M.D. Pennsylvania.

MYLAN PHARMACEUTICALS INC., Plaintiff,

v.

MERCK & CO., INC., Defendant.

No. Civ. 1:05-CV-1416.

Oct. 28, 2005.

Amy D. Brody, Christine J. Siwik, William A. Rakoczy, Rakoczy Molino Mazzochi Siwik LLP, Chicago, IL, Charles W. Rubendall, II, Keefer, Wood, Allen and Rahal, Harrisburg, PA, for Plaintiff.

Edward W. Murray, Mary J. Morry, Merck & Co., Inc., Rahway, NJ, Robert L. Baechtold, Stevan J. Bosses, Fitzpatrick, Cella, Harper & Scinto, New York, NY, Brian P. Downey, Justin G. Weber, Pepper Hamilton LLP, Harrisburg, PA, for Defendant.

Jury Trial Demanded

RAMBO, J.

MEMORANDUM

***1** Before the court are Defendant Merck & Co, Inc.'s ("Merck") Motion to Dismiss (Doc. 19) and Contingent Motion to Transfer Under 28 U.S.C. § 1404(a) (Doc. 22). The parties have briefed the issues and the matters are ripe for disposition. For the reasons that follow, the court will grant Defendant's motion to dismiss because the court lacks subject matter jurisdiction. Accordingly, the court will deny Defendant's contingent motion to transfer as moot.

I. *Background*

A. *The Hatch-Waxman and Medicare Amendments*

The Federal Food, Drug, and Cosmetic Act of 1938 ("FDDCA"), 21 U.S.C. §§ 1 et seq., governs the procedures for the approval of pioneer and generic drugs. The FFDCA's statutory scheme for the approval of generic drugs was first modified by the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"), Pub.L. No. 98-417, 98 Stat. 1585 (1984). In 2003, Congress further modified the generic drug approval scheme when it enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Amendments"), Pub.L. No. 108-173, 117 Stat.2066 (2003) [FN1] to prevent abuses associated with the patent code's declaratory judgment provisions.

> FN1. The Hatch-Waxman Act is codified at 35 U.S.C. § 271. The relevant portions of the FFDCA, as modified by the Hatch-Waxman and Medicare Amendments, are codified at 21 U.S.C. § 355.

Under the current statutory scheme, pioneer drug manufacturers must file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") to obtain approval to manufacture and market a drug. 21 U.S.C. §§ 355(a)-(b)(1). An NDA contains comprehensive information demonstrating the drug's safety and efficacy. *See id.* NDA-holders are also required to notify the FDA of all patents that cover the new drug. 21 U.S.C. §§ 355(b)(1), (c)(2). The FDA then lists the patents in what is commonly referred to as the "Orange Book." [FN2]

> FN2. The official name of the publication is "Approved Drug Products with Therapeutic Equivalence Evaluations."

A manufacturer of a generic version of an approved drug may then submit an Abbreviated New Drug Application ("ANDA") to the FDA, in which it may rely on the NDA's safety and efficacy studies. 21 U.S.C. §§ 355(j)(1), (2)(A)(I). An ANDA must include information establishing that the generic drug is the bioequivalent of the approved pioneer drug. 21 U.S.C. § 355(j)(2)(A). An ANDA must also contain one of four certifications regarding any patents that are listed in the Orange Book for the pioneer drug:

(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. §§ 355(j)(2)(A)(vii)(I-IV). "These are commonly referred to as paragraph I, II, III, and IV certifications."

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Teva Pharms. USA, Inc. v. Pfizer Inc., 395 F.3d 1324, 1328 (Fed.Cir.2005).

When an ANDA filer wants to sell its generic drug product before a listed patent has expired, it must file a paragraph IV certification. When filing a paragraph IV certification, the ANDA filer must also notify the owner of any relevant patents and NDA holder and provide them with a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. §§ 355(j)(2)(B)(i), (iv).

*2 The filing of the ANDA triggers a forty-five-day period during which the ANDA applicant is barred from filing a declaratory judgment action. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent holder files an infringement action within that forty-five-day period, the FDA may not approve the ANDA for thirty months, unless the suit is resolved or the patent expires earlier. *Id.* If the patent holder does not file an infringement suit during the forty-five-day period, the FDA may approve the ANDA. *Id.*

As an incentive to encourage early ANDA applicants, the Hatch-Waxman amendments provide for a 180-day marketing exclusivity period for the first ANDA applicant to make a paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv). The Medicare Amendments, which apply to the instant case, made various changes with respect to the exclusivity period provisions, including "forfeiture provisions" that identify the circumstances in which the 180-day exclusivity period can be forfeited [FN3] 21 U.S.C. § 355(j)(5)(D).

> FN3. The Medicare Amendments were enacted on December 8, 2003; the forfeiture provisions are applicable to ANDAs "filed after December 8, 2003, for which no paragraph IV certification was made before December 8, 2003." *Teva*, 395 F.3d at 1329; Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1102(b). Mylan Pharmaceuticals, Inc. notified Merck about its ANDA and paragraph IV certification by letter dated April 26, 2005.

The exclusivity period ensures that the only generic drug on the market during that time is that of the first ANDA filer because the FDA may not approve a subsequent ANDA for the same drug during the exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv). The exclusivity period is triggered by the first commercial marketing of the drug (by either the pioneer drug owner or the first ANDA filer.) *Id.* However, it can also be triggered earlier, on the date on which a court enters judgment that the patent is invalid or not infringed, 21 U.S.C. § 355(j)(5)(B)(iii). Thus, an action involving a subsequent ANDA filer can result in a judgment that triggers the exclusivity period. *See id.*

The Medicare Amendments also added civil action provisions which state that if neither the patent-holder or NDA-holder brings an infringement action during the forty-five day period following receipt of the paragraph IV certification, the ANDA applicant may "bring a civil action ... for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval," in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act). 21 U.S.C. § 355(j)(5)(C)(i).

B. *Factual Background*

Merck developed a formulation of finasteride, which it markets under the brand name PROSCAR®,[FN4] a drug used to treat symptomatic benign prostatic hyperplasia (enlarged prostate, known as "BPH"). Merck holds NDA No. 20-180, which the FDA approved, allowing Merck to market and sell the PROSCAR® finasteride formulation. Merck also holds several patents that relate to its finasteride product, including United States Patent Nos.: 1) 4,760,071 ("the '071 patent"), issued on July 26, 1988, which covers the compound itself; 2) 5,886,184 ("the '184 patent"), issued on May 23, 1999, which covers a particular crystalline form of finasteride; 3) 6,046,183 ("the '183 patent"), issued on April 4, 2000, which covers a method of treatment for BPH using finasteride in combination with another specific drug; and 4) 5,942,519 ("the '519 patent"), issued on August 25, 1999, which covers using finasteride specifically for patients who are suffering from precipitated acute urinary retention ("PAUR"). All four patents are listed in the FDA's Orange Book for PROSCAR®.

> FN4. Mylan also markets finasteride under the brand name PROPECIA®

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*3 On April 30, 2002, and July 2, 2003, Ivax Pharmaceuticals Inc., ("Ivax") submitted ANDAs seeking to market generic forms of Merck's PROSCAR® finasteride product. Ivax also notified Merck regarding its paragraph IV certifications for the '184 and '183 patents. Merck did not sue Ivax during the subsequent forty-five-day period and has not sued Ivax to date. Ivax was the first ANDA filer and is thus entitled to the benefit of the 180-day exclusivity period.

On April 26, 2005, Mylan notified Merck regarding Mylan's ANDA for the same product, along with paragraph IV certifications for the '184 and '183 patents. Mylan also submitted a section viii statement, pursuant to 21 U.S.C. § 355(j)(2)(A)(viii), stating that the '519 patent claims a method of using finasteride for which Mylan is not seeking approval. Merck did not sue Mylan during the subsequent forty-five-day period and has not sued Merck to date. The only communication that Mylan has received from Merck regarding its generic finasteride product is a letter dated June 9, 2005, indicating that Merck did not intend to sue within the forty-five-day period. Merck has declined to covenant not to sue Mylan for infringement of the patents.

To date, no company has filed a paragraph IV certification for the '071 patent, which expires on June 19, 2006. Both Ivax and Mylan have filed paragraph III certifications that they will wait until after the '071 expiration date to market their generic finasteride products. Merck has indicated that because finasteride is not covered *per se* by the '184, '183, or '519 patents, it is possible for a generic competitor to make and sell a generic finasteride product without infringing any of those patents

C. *Procedural History*

Mylan Pharmaceuticals, Inc. ("Mylan") filed a Complaint on July 14, 2005, seeking a declaratory judgment that its generic finasteride drug product does not and will not infringe the '184, '183, and '519 patents. Merck filed a Motion to Dismiss (Doc. 19) on August 29, 2005, for lack of subject matter jurisdiction, claiming that no case or controversy exists. Because the court finds no case or controversy, the court will grant Merck's Motion to Dismiss and dismiss the Complaint for lack of subject matter jurisdiction.[FN5]

FN5. Merck also filed a Contingent Motion to Transfer Under 28 U.S.C. § 1404(a). (Doc. 22.) The court will deny that motion as moot.

II. *Legal Standard*

" 'A motion to dismiss under Rule 12(b)(1) challenges the jurisdiction of the court to address the merits of the plaintiff's complaint." ' *Vieth v. Pennsylvania*, 188 F.Supp.2d 532, 537 (M.D.Pa.2002) (quoting *Ballenger v. Applied Digital Solutions, Inc.*, 189 F.Supp.2d 196, 199 (D.Del.2002)). The motion should be granted where the asserted claim is "so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as not to involve a federal controversy." *Coxson v. Pennsylvania*, 935 F.Supp. 624, 626 (W.D.Pa.1996) (citing *Growth Horizons v. Delaware County*, 983 F.2d 1277, 1280-81 (3d Cir.1993)).

*4 A motion to dismiss under Rule 12(b)(1) may present either a facial or factual challenge to subject matter jurisdiction. *See Carpet Group Int'l v. Oriental Rug Imps. Ass'n*, 227 F.3d 62, 69 (3d Cir.2000). This case presents a facial challenge because Defendant does not dispute, at this juncture, the jurisdictional facts alleged in the Complaint. *See* 2 James Wm. Moore et al., Moore's Federal Practice ¶ 12.30[4] (3d ed.1999) (explaining the difference between a facial and factual challenge to subject matter jurisdiction pursuant to Rule 12(b)(1)). Therefore, the court must accept the facts alleged in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Zinermon v. Burch*, 494 U.S. 113, 118, 110 S.Ct. 975, 108 L.Ed.2d 100 (1990); *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir.2000).

III. *Discussion*

A. *The Declaratory Judgment Act*

The Declaratory Judgment Act provides in relevant part that "[i]n a case of actual controversy within its jurisdiction ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28

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U.S.C. § 2201(a). The Act's actual controversy requirement parallels the federal jurisdictional requirement found in Article III of the Constitution. *Teva*, 395 F.3d at 1331.

Essentially, the court must determine " 'whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.' " *Id.* (quoting *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed.Cir.1996)). If no actual controversy exists, then the court lacks jurisdiction to hear the case. *Id.* at 1332. However, even when the court determines that there is a controversy, it may exercise its discretion to decline jurisdiction. *Id.*

The inquiry regarding whether an actual controversy exists in a suit seeking a declaration of patent non-infringement or invalidity is two-fold. *Id.*
There must be both (1) an explicit threat or other action by the patentee [that] creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff [that] could constitute infringement, or concrete steps taken with the intent to conduct such activity.

Id. In addition, with respect to the reasonable apprehension prong, " '[w]hen the defendant's conduct, including its statements falls short of an express charge, one must consider the totality of the circumstances in determining whether that conduct meets the first prong of the test.' " *Id.* (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed.Cir.1988))

Mylan and Merck agree that Mylan's submission of the paragraph IV certification satisfies the second prong of the test. Accordingly, the issue before the court is whether any of Merck's conduct established a reasonable apprehension that Merck would sue Mylan for infringement.

B. *Analysis*

*5 Mylan acknowledges that Merck has not explicitly stated that it intends to sue Mylan for infringement of its finasteride patents (Def.'s Opp'n to Pl.'s Mot. to Dismiss at 12.) ("Merck has said nothing to Mylan or this Court about its intentions *after* the expiration of this 45-day period.") Accordingly, the court will consider whether Merck's conduct, under the totality of circumstances, establishes a reasonable apprehension that Merck will sue Mylan for infringement of the patents. *Teva*, 395 F.3d at 1332.

Mylan argues that the following Merck acts establish grounds for its reasonable apprehension of an infringement suit: 1) Merck's listing of the finasteride patents in the Orange Book; 2) Merck's prior history of defending its patents through litigation; 3) Merck's public statements that it will defend its finasteride patents; and 4) Merck's refusal to covenant not to sue Mylan for infringement. Mylan also argues that the Medicare Amendments civil suit provision (21 U.S.C. § 355(j)(5)(C)) provides a means to assert subject matter jurisdiction subject only to Article III requirements, which it believes to be different than the requirements of the two-prong test. Upon consideration of all of the circumstances, and in accordance with Federal Circuit precedent,FN6 the court finds that Mylan's arguments fail to establish a reasonable apprehension of suit.

> FN6. Patent law appeals are heard by the Court of Appeals for the Federal Circuit; thus the law of the Federal Circuit applies. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 n. 4 (Fed.Cir.1992).

1. *Orange Book Listing*

Mylan argues that Merck's listing of the patents in the Orange Book is sufficient on its own to establish a reasonable apprehension of suit because it represents Merck's position that it could reasonably assert an infringement suit with respect to its patents. *See* 21 U.S.C. § 355(b)(1) (providing that NDA applicants must file notice of any patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug"-the FDA then lists these patents in the Orange Book). However, without more, Merck's compliance with the statutory listing requirement "should not be construed as a blanket threat to potential infringers" by patent owners. *Teva*, 395 F.3d at 1333. The Orange Book listing is insufficient to satisfy the objective intent to sue standard required to establish an actual controversy between a patentee and "any ANDA filer

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who submits a paragraph IV certification with respect to the patent." *Id.* Thus, Mylan's argument that Merck's Orange Book listing alone establishes a reasonable apprehension of suit fails.

2. *History of Litigation*

Mylan argues that Merck's history of asserting its patents, including its finasteride patents, as well as other patents, through litigation involving other companies establishes a reasonable apprehension of suit here. Mylan relies on Merck's litigation against Dr. Reddy's specifically and Merck's litigation history generally. As a threshold matter, Merck's infringement litigation history is relevant but not dispositive. *Id.* The determination of whether there is an actual controversy between the parties turns on "the Article III mandate that the injury in fact be 'concrete,' and 'actual or imminent, not conjectural or hypothetical.' " *Id.* (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273, 61 S.Ct. 510, 85 L.Ed. 826 (1941)).

***6** First, the court notes the similarities between Mylan's position here and Teva's in *Teva,* where the Federal Circuit court held that Teva failed to demonstrate a reasonable apprehension of suit. *Id.* at 1334. The similarities include Mylan's "virtual conce[ssion] that [Merck] will not bring immediate suit for infringement of the [finasteride patents]," FN7 and the fact that "[Merck] need not sue [Mylan] immediately" because the FDA cannot approve Mylan's ANDA for generic finasteride before Ivax's 180-day exclusivity period expires. *See id.*

> FN7. Mylan points to Merck's suit against Dr. Reddy's two years after the filing of Dr. Reddy's ANDA for generic finasteride/PROPECIA® and speaks in terms of Merck's possible "future intentions."

Moreover, the nature of Merck's litigation against Dr. Reddy's regarding two of its finasteride patents and against other companies regarding other patents is insufficient to establish that, under the instant circumstances, Mylan has a reasonable apprehension of suit. Merck's infringement suit against Dr. Reddy's involving the finasteride patents, although relevant, does not on its own convey a reasonable apprehension of suit to Mylan. Although the *Arrowhead* court determined that reasonable apprehension existed where a patentee had previously filed suit involving the same patent against another company, it did so where there were additional factors that, taken together, satisfied the totality of circumstances test. 846 F.2d at 737. An infringement suit against another filer, even to protect the same patent, does not conclusively establish a reasonable apprehension of suit. *See Dr. Reddy's Labs., Ltd. v. Pfizer, Inc.*, No. Civ. A. 03-CV-726, 2003 WL 21638254, at *6 (D.N.J. Jul.8, 2003)* (Pfizer's suit against first ANDA filer and involving same patent did not establish reasonable apprehension of suit for subsequent ANDA filer).

Mylan points to nothing more than the bare fact that Merck filed suit against Dr. Reddy's for finasteride patents for a different brand name product (PROPECIA®). It suggests no other similarities between the Dr. Reddy's circumstances and its own and, in fact, fails to identify specifically which finasteride patents are at issue in that action (Mylan identifies them only as "other Merck-owned finasteride patents). In addition, Merck has not sued Ivax, the first filer here, or any other filer regarding the finasteride patents for PROSCAR®. Accordingly, the court finds that Merck's conduct with respect to Dr. Reddy's fails to establish a reasonable apprehension of suit for Mylan.

Merck's history of enforcing other patents against other companies, although relevant, also fails to establish a reasonable apprehension of suit for Mylan. A patentee's history of enforcing patents generally does not in and of itself provide any indication regarding the patentee's intentions regarding other patents. *See Mutual Pharm. Co. v. Pfizer Inc.*, 307 F.Supp.2d 88, 93-94 (D.D.C.2004); *Dr. Reddy's Labs.*, 2003 WL 21638254, at *7. Moreover, [i]n cases where courts have found prior litigation sufficiently threatening, either (1) the defendant referenced that litigation in some communication to the plaintiff, or (2) there was ongoing litigation between the parties over a series of closely related patents involving the same technology." *Apotex, Inc. v. Pfizer Inc.*, 385 F.Supp.2d 187, 194 (S.D.N.Y.2005)* (internal citations omitted). No such communication or ongoing litigation between the parties involving the same technology exist here. Accordingly, Merck's prior history of litigation re-

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garding its other patents fails to establish a reasonable apprehension of suit for Mylan.

3. *Public Statements*

*7 Mylan also bases its reasonable apprehension argument on statements Merck published in its annual and quarterly reports. The statement that "[Merck] intends to vigorously defend its patents, which it believes are valid, against infringement by generic companies attempting to market products prior to the expiration dates of such patents," FN8 on its own, fails to establish a reasonable apprehension of suit for Mylan. "[A] patent holder's statement that it intends to enforce its patent does not [necessarily] create a reasonable apprehension of suit." *Torpharm, Inc. v. Pfizer Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756, at *41 (D.Del. June 28, 2004), *vacated as moot*, 125 Fed. Appx. 987 (Fed.Cir.2005) (determined to be moot when Pfizer entered into covenant not to sue Torpharm for infringement) (citing *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051, 1054 (Fed.Cir.1995).

> FN8. The relevant language in its entirety reads "Generic pharmaceutical manufacturers have submitted ANDAs to the FDA seeking to market in the United States a generic form of *Fosomax, Prilosec* and *Propecia* prior to the expiration of the Company's (and AstraZeneca's in the case of *Prilosec*) patents concerning these products. The generic companies' ANDAs generally include allegations of non-infringement, invalidity and unenforceability of the patents. Generic manufacturers have received FDA approval to market a generic form of *Prilosec*. The Company has filed patent infringement suits in federal court against companies filing ANDAs for generic alendronate and finasteride and AstraZeneca and the Company have filed suits in federal court against companies filing ANDAs for generic omeprazole. Similar patent challenges exist in certain foreign jurisdictions. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by generic companies attempting to market products prior to the expiration dates of such patents."

Merck's statement is "of a general nature, directed to [an] overall strategy of enforcing [Merck's] patent rights against generic competition" and is "not specifically directed against [Mylan], nor is there any evidence suggesting that it was made with [Mylan] in mind." *Id.* (declining to find that a statement that Pfizer would "continue aggressively to defend challenges to [its] intellectual property" in a press release regarding an infringement suit against the first ANDA filer for the same patent implicated by Torpharm's ANDA). Moreover, courts have found patentee communications to be threatening in contexts where they 1) specifically link the prospect of litigation to questions concerning an ANDA filer's ability to make a generic drug properly without the patents or 2) otherwise link a policy of enforcement or likelihood of litigation to a specific generic company in letters or other communications, thus implicitly conveying a threat of litigation. *See, e.g., Dr. Reddy's Labs., Ltd. v. aaiPharma Inc.*, No. 01 Civ. 10102(LAP), 2002 WL 31059289, at *3-4 (S.D.N.Y. Sept.13, 2002) (patentee stated in two *Wall Street Journal* articles that it would be "unlikely" or "difficult for" generic companies to make Prilosec properly without using patents and that if generic companies "refused to pay" patentee for licenses, a "threat of a lawsuit" existed); *DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397, 1401 (Fed.Cir.1995) ("Bristol-Myers' stated policy, *together with letters* sent by Bristol-Myers to DuPont Merck/Endo and Mylan relating to the '776 patent, create a reasonable apprehension on the part of DuPont Merck/Endo and Mylan.") (emphasis added); *Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F.Supp.2d 311, 316 (S.D.N.Y.2003) (Kos' statement that it would "aggressively enforce" its patents was made in a press release discussing the underlying litigation between the parties).

No such communications have occurred between Merck and Mylan. The only specific communications referenced here are Merck's June 9, 2005 letter stating that it would not sue Mylan for infringement within the forty-five-day period and its October 5, 2005 letter declining Mylan's proposed covenant and stipulation of non-infringement. The June 9 letter addressing Merck's intentions for the forty-five-day period makes no other representations about Merck's intentions and contains no reference to or statement of a policy of patent enforcement on the part of Merck.

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*8 The October 5 letter declining to enter into a covenant or stipulations similarly contains no representations about Merck's intentions regarding a law suit. The letter simply conveys Merck's beliefs that it is not obligated to enter into a covenant and that the instant action is inappropriate. Thus, Mylan fails to identify any communications from Merck that would recast its stated general enforcement strategy in a way that would establish a reasonable apprehension of suit for Mylan.

4. *Refusal to Covenant*

Mylan also argues that Merck's refusal to grant Mylan a covenant not to sue supports its contention that a reasonable apprehension of suit exists. Mylan correctly notes that this is a relevant factor; however, it is not dispositive. *Teva*, 395 F.3d at 1333 (citing *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed.Cir.1993). Moreover, Merck is under no statutory obligation to provide a covenant or otherwise assure Mylan that it will not sue for infringement. *See Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. Civ. A. 03CV10167RGS, WL 2003 WL 22888848, at *4 (D.Mass. Dec.8, 2003), *aff'd Teva*, 395 F.3d 1324. Mylan argues that Merck's statement that it would not sue within the forty-five-day period following notice of Mylan's ANDA, without a covenant not to sue, includes the unspoken inference of "yet." This argument is simply too speculative to establish a reasonable apprehension of suit for Mylan under the instant circumstances.

5. *Statutory Civil Suit Provision*

Finally, Mylan argues that the Medicare Amendments, through the declaratory judgment provision, provide a means of satisfying Article III's requirements without satisfying the reasonable apprehension of suit prong of the two-part test. The Federal Circuit squarely addressed this issue in *Teva* and

conclude[d] that the plain language of the statute, as well as the legislative history, support the conclusion that Congress did not intend for the Medicare Amendments to cause courts to alter the requirement of the two-part test that a declaratory judgment plaintiff must demonstrate a "reasonable apprehension" of suit to establish Article III jurisdiction. [The] traditional two-part test remains good law....

395 F.3d at 1337. Accordingly, the court will rely upon the traditional two-part test in making its finding that none of the above factors relied upon by Mylan, taken alone or taken together, establish a reasonable apprehension of suit. Therefore, the court lacks subject matter jurisdiction to consider Mylan's request for declaratory judgment.

IV. *Conclusion*

For the foregoing reasons, the court grants Merck's Motion to Dismiss for lack of subject matter jurisdiction. Accordingly, the court denies Merck's Contingent Motion to Transfer Under 28 U.S.C. § 1404(a) as moot.

ORDER

In accordance with the accompanying memorandum of law, IT IS HEREBY ORDERED THAT:

1) Defendant's Motion to Dismiss (Doc. 19) is GRANTED;

*9 2) Defendant's Contingent Motion to Transfer Under 28 U.S.C. § 1404(a) (Doc. 22) is DENIED as MOOT;

3) Plaintiff's oral request for oral argument on this motion is deemed MOOT; and

4) The Clerk of Court is directed to close the file.

M.D.Pa.,2005.
Mylan Pharmaceuticals Inc. v. Merck & Co., Inc.
Slip Copy, 2005 WL 2850137 (M.D.Pa.)

Briefs and Other Related Documents (Back to top)

- 2005 WL 3136824 (Trial Motion, Memorandum and Affidavit) Reply Memorandum of Law in Support of Defendant's Contingent Motion to Transfer Under 28 U.S.C. | 1404(A) (Oct. 26, 2005) Original Image of this Document (PDF)
- 2005 WL 3136820 (Trial Motion, Memorandum and Affidavit) Mylan Pharmaceuticals Inc.'s Memorandum of Law in Opposition to Merck's Motion to Dismiss (Oct. 4, 2005) Original Image of this Document (PDF)
- 2005 WL 2613067 (Trial Motion, Memorandum and Affidavit) Memorandum of Law in Support of Defendant's Mo-

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tion to Dismiss Plaintiff's Complaint (Aug. 29, 2005) Original Image of this Document (PDF)
• 2005 WL 2613070 (Trial Motion, Memorandum and Affidavit) Memorandum of Law in Support of Defendant's Contingent Motion to Transfer under 28 U.S.C. | 1404(A) (Aug. 29, 2005) Original Image of this Document (PDF)
• 2005 WL 2233973 (Trial Pleading) Complaint for Declaratory Judgment (Jul. 14, 2005) Original Image of this Document (PDF)

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EXHIBIT G

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Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2003 WL 21638254 (D.N.J.)
(Cite as: Not Reported in F.Supp.2d)

C

Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court,D. New Jersey.

DR. REDDY'S LABORATORIES, LTD. and Dr. Reddy's Laboratories, Inc. Plaintiffs,

v.

PFIZER INC. Defendant

No. Civ.A.03-CV-726(JAP).

July 8, 2003.

Brian T. Moriarty, Budd Larner Rosenbaum Greenberg & Sade, Short Hills, NJ, for Plaintiff.

David E. De Lorenzi, Gibbons Del Deo Dolan Griffinger & Vecchione, Newark, NJ, Dimitrios T. Drivas, Admitted ProHac Vice, Jeffrey J. Oelke, Admitted ProHac Vice, Adam Gahtan, Admitted ProHac Vice, White & Case, New York, NY, for Defendant.

OPINION

PISANO, J.

***1** Defendant Pfizer Inc. ("Pfizer") moves to dismiss this Complaint for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. Plaintiff Dr. Reddy's Laboratories ("DRL") seeks a declaratory judgment pursuant to 28 U.S.C. § 2201 that its generic version of setraline hydrochloride does not infringe upon U.S. Patent No. 5,248,699 (the " '699 patent"). Defendant Pfizer currently markets the brand name version of setraline hydrochloride, Zoloft, which is covered both by the '699 Patent and U.S. Patent No. 4,356,518 (the " '518 patent").

I. Statement of Facts

Zoloft, which has been approved by the FDA for the treatment of mood and anxiety disorders, is covered by two different United States patents; the '518 patent and the '699 patent. The '518 patent is directed towards the compound setraline itself, and this patent expires on December 30, 2005. The '699 patent covers setraline in a particular crystalline form ("Form I polymorph") and expires on September 28, 2010. Pfizer has filed both of these patent numbers and expiration dates in the "Orange Book," properly known as *Approved Drug Products with Therapeutic Equivalence Evaluations* [FN1] Because FDA has granted a six month extension on exclusivity for the Zoloft product for the treatment of the pediatric population, any generic version of setraline hydrochloride product may not be marketed and sold to the public until June 30, 2006.

FN1. U.S. Patent No. 4,962,128 (the " '128 patent") also covers the Zoloft product, and is listed by Pfizer in the Orange Book. The '128 patent is not at issue in this action.

Plaintiff DRL has filed an Abbreviated New Drug Application ("ANDA") and seeks to market and sell a generic version of setraline in tablet form. By filing the ANDA, the maker of the generic version of the drug must demonstrate that the new drug is bioequivalent to the brand name version of the drug already approved by FDA through a New Drug Application ("NDA"). 21 U.S.C. § 355(j)(2). A party that files an ANDA seeking approval to market a generic version of a drug covered by patents listed in the Orange Book must include a certification with respect to every listed patent. 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94.

DRL made a "paragraph III certification" with respect to the '518 patent. 21 U.S.C. § 355(j)(2)(A)(vii)(III). The paragraph III certification indicates that the '518 patent covers the drug, will expire in December 2005, and that DRL will not market its generic product until the expiration of the patent. Because the FDA has granted a six month exclusivity extension to Pfizer for the Zoloft product, DRL may not receive FDA final approval to market its setraline tablets until June 30, 2006, at the earliest.

DRL made a "paragraph IV certification" with respect to the '699 patent, which expires on September 28, 2010. DRL's certification regarding the '699 patent is a representation that this patent is invalid, unenforceable, and/or will not be infringed by DRL's generic setraline product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The basis of this certification is DRL's representation that its generic setraline tablets are a particular crystalline form ("Form II polymorph") that is not covered by the claims in the '699 patent (covering Form I polymorphs). Based on this ANDA submission, DRL would not be required to wait until the expiration of the '699 patent

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in 2010 before marketing its generic setraline product.

*2 In 1999, Ivax (a manufacturer of generic drugs) submitted an ANDA application to the FDA to market a generic setraline tablet, and filed a paragraph IV certification with respect to the '699 patent, and a paragraph III certification with respect to the '518 patent. Ivax (then Zenith Goldline) notified Pfizer on December 17, 1999 of this ANDA application and the paragraph IV certification with respect to the '699 patent. Within 45 days of this notification, Pfizer filed suit against Ivax alleging infringement of the '699 patent,FN2 and the parties eventually settled this dispute.FN3 The terms of the settlement agreement itself neither advance nor delay the date on which Zenith sought to market its generic product. Pfizer did not file an infringement action against DRL within 45 days after being notified of the paragraph IV certification regarding the '699 patent.

FN2. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), known as a "stay-put" provision, an infringement action brought within 45 days of a paragraph IV certification creates an automatic thirty month stay of approval of the ANDA application, unless there is an intervening court decision regarding the validity or infringement of the relevant patent, which might shorten this period or extend the period.

FN3. Pfizer also asserted that Ivax infringed upon the '128 patent, which is not at issue in the current action.

II. Standard for Declaratory Judgment

The Declaratory Judgment Act permits a court in a case of actual controversy within its jurisdiction to "declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a). Even when an actual controversy exists, the assumption of this jurisdiction rests within "the unique and substantial discretion" of federal courts, as the "statute provides that a court '*may* declare the rights and other legal relations of an interested party[.]" ' *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995) (citing 28 § 2201(a)). In any event, the Declaratory Judgment "may not be a medium for securing an advisory opinion in a controversy which has not arisen." *Coffman v. Breeze Corps. Inc.*, 323 U.S. 316, 324 (1945) (citations omitted).

The Federal Circuit has held in patent cases that an actual controversy exists where there is "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or taken with the intent to conduct such activity." *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed.Cir.1999) (quoting *BP Chems. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed Cir.1993)).FN4 In showing a reasonable apprehension of facing an infringement suit, the plaintiff does not need to demonstrate an actual or expressly threatened lawsuit, but must demonstrate "conduct that rises to a level sufficient to indicate an intent [of the patentee] to enforce its patent, i.e., to initiate an infringement action." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811 (Fed.Cir.1996) (citations omitted). However, subjective impressions of the plaintiff are insufficient to satisfy the requirement, and the court must find objective facts considering the "totality of the circumstances" at the time the complaint was filed. *Arrowhead Indus. Water v. Ecolochem*, 846 F.2d 731, 736 (Fed.Cir.1988).

FN4. The second prong requiring concrete steps with the intent to conduct infringement activity has also been formulated as "meaningful preparation" towards infringing activity. *See Lang v. Pac. Marine & Supply Co., Ltd.*, 895 F.2d 761, 764 (Fed.Cir.1990). Both parties concede that the substantive test remains the same regardless of the verbal formulation. *See* Pl's Opp. Br. at 12 n. 5; Def's Reply Br. at 2.

*3 The second prong of this test requires infringement activity, or meaningful preparation along with the intent to commit infringing activity. The allegations supporting such a declaratory action must demonstrate an "immediate and real controversy" that would convey jurisdiction under the Declaratory Judgment Act. *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed.Cir.1992). This prong insures that the plaintiff has a "true interest to be protected," and prevents courts from issuing advisory opinions about events that are merely foreseeable. *Arrowhead*, 846 F.2d at 736. However, the Federal Circuit has also affirmed the

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finding of no case or controversy jurisdiction if the allegedly infringing product was "years away from potential FDA approval" and the manufacturer was prohibited during that time from committing acts that would constitute infringement. *Id.* at 1526-27

III. DRL's Allegation of an Immediate and Real Controversy

DRL must demonstrate that there is an immediate and real controversy that would allow this Court to exercise jurisdiction under the Declaratory Judgment Act. Pfizer contends that DRL's allegations do not support an actual controversy finding because DRL does not have "immediate intention and ability" to produce generic setraline. *Bristol-Myers Squibb Co. v. Ivax Corp.*, 77 F.Supp.2d 606, 618 (D.N.J.2000). Furthermore, Pfizer argues that DRL is "years away from potential FDA approval" and thus does not have the ability to commit a potentially infringing act. Def's Reply Mem. Br. at 3 (citing *Telectronics*, 982 F.2d at 1527). Because DRL may not receive final FDA approval for its ANDA application until at least June 30, 2006, when the '518 patent exclusivity period expires, DRL's allegations "lacked sufficient immediacy and reality to meet the actual controversy requirement under the Declaratory Judgment Act," according to Pfizer. *Id.*

However, Pfizer does not properly address the entire immediate and real controversy prong of the test for case or controversy jurisdiction under the Declaratory Judgment Act. This requirement can be satisfied by either "present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Amana Refrigeration*, 172 F.3d at 855. While Pfizer relies upon a Federal Circuit case regarding a claim of future patent infringement of a mechanical device and other decisions from this district, the Hatch-Waxman Act itself specifically defines the submission of an ANDA application as an act of infringement when the purpose of the filing is to engage in the manufacture and sale of a drug claimed in a patent that has not expired. 35 U.S.C. § 271(e)(2)(A). In interpreting the plain language of this statute, this Court is mindful that when "the terms of a statute are unambiguous, judicial inquiry is complete, except in rare and exceptional circumstances." *Rubin v. United States*, 449 U.S. 424, 430 (1981).

*4 The Federal Circuit has interpreted this statutory provision as defining infringement to meet the case or controversy requirement under the Declaratory Judgment Act. In *Glaxo v. Novopharm*, 110 F.3d 1562, 1569 (Fed.Cir.1997), the circuit explicitly stated " § 271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." The court recognized that this statutory definition of infringing activity was premised upon the future marketing and sale of the product, and the determination was whether future approval of the ANDA would ultimately infringe upon the patent. There is no principled reason to distinguish a declaratory action for non-infringement in this situation from the converse situation in *Novopharm* of a patentee suing for future infringement based upon the ANDA. *See Dupont Merck Pharm. Co. v. Bristol-Myers Squibb Co.* 62 F.3d 1397, 1402 (Fed.Cir.1995) (finding that the filing of a paragraph IV certification for a patent in the submission of an ANDA is infringement). Thus, DRL's present activity of filing an ANDA to produce generic setraline along with a paragraph IV certification for the "699 patent is present activity which constitutes infringement because such activity is defined as infringement under 35 U.S.C. § 271(e)(2).

Pfizer contends that DRL's submission of an ANDA does not constitute infringement or meaningful preparation for infringing activity because the ANDA cannot receive FDA approval until June 30, 2006 when the "518 patent expires. Pfizer relies upon *Telectronics Pacing Sys. v. Ventritex*, 982 F.2d 1520 (Fed Cir.1992), where the Federal Circuit affirmed a finding of no jurisdiction where a patentee filed suit for infringement based on a device undergoing clinical trials and was "years away from potential FDA approval." *Id.* at 1527. Contrary to the facts presented in *Telectronics*, DRL has in this instance committed acts that are defined in the Hatch-Waxman Act as infringement. Furthermore, the decision in *Telectronics* was based on the possibility that the eventual device as modified might significantly be changed at the end of clinical trials. In this instance, DRL prepared and filed and ANDA submission and filed a paragraph IV certification with respect to the "699 patent. In making this submission, DRL committed a technical act of infringement in stating that their product would be bioequivalent to Zo-

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loft, and then represented that it would not infringe upon the "699 patent, or that the patent was invalid.

Pfizer further relies upon a case from this district which allegedly supports the proposition that even an ANDA applicant might not demonstrate sufficient immediacy to create a justiciable case or controversy. In *Bristol-Myers Squibb Co. v. Ivax Corp.*, 77 F.Supp.2d 606, 619 (D.N.J.2000), the court found no jurisdiction because of the failure to demonstrate the requisiste immediacy. In that case, the party defending a counterclaim for declaratory judgment for non-infringement had filed a supplemental NDA, which delayed any approval for the initial ANDA applicant until 2004. Furthermore, the court did not address the plain language of the statute defining the submission of an ANDA as an act of infringement, nor the controlling authority from the Federal Circuit which has interpreted the filing of a paragraph IV certification with an ANDA submission as technical infringement.[FN5]

> FN5. The Court further notes that Pfizer relies upon *NeoRx Corp. v. Immunomedics*, 877 F.Supp. 202, 214 (D.N.J.1994), but this case does not involve the statutory provision at issue here. While Plaintiff DRL cites *Hoechst Marion Roussel v. Par Pharm.*, 39 U.S.P.Q.2d 1363, 1367 (D.N.J.1996), this opinion only mentions the issue of the effect of an ANDA submission in a brief paragraph in addressing a motion for reconsideration.

*5 Because the Plaintiff has adequately demonstrated that there is a real case or controversy at issue in the litigation by the submission of an ANDA, this Court finds that the infringement prong of the case or controversy test for jurisdiction has been met, and will address the second prong of reasonable apprehension of litigation.

IV. Reasonable Apprehension of Litigation

Plaintiff DRL must show a specific threat or other action by Pfizer that would create reasonable apprehension of suit in order meet the second prong of the test for case or controversy jurisdiction under the Declaratory Judgment Act.[FN6] This standard does not require direct threats of suit, but the words and actions of the patentee may indirectly place the declaratory plaintiff in reasonable apprehension of suit. *BP Chems. Ltd.*, 4 F.3d at 979. While mindful to consider all the circumstances, the District Court may only find an actual controversy based upon the objective actions of the patentee, not the subjective impressions of the plaintiff. *Indium Corp of America v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed.Cir.1985). The objective actions of the patentee must rise " 'to a level sufficient to indicate an intent to enforce its patent', i.e., to initiate an infringement action." *EMC Corp.* 89 F.3d at 811 (citation omitted).

> FN6. The Court notes that, in any case, such jurisdiction cannot exceed the limits of the U.S. Constitution, art. III, § 2, cl. 1.

In support of its assertion that this Court may exercise jurisdiction, DRL lists several key factors which taken together create a reasonable apprehension of suit. These factors include: (1) Pfizer has listed the '699 patent in the Orange Book, indicating that a generic form of Zoloft could infringe its patent; (2) Pfizer currently refuses to provide DRL with a covenant not to sue and has shown hostility towards DRL in public statements; (3) Pfizer has aggresively asserted its patent rights in other situations; (4) Pfizer has sued Ivax, the first generic manufacturer of setraline, alleging infringement of the '699 patent; (5) Pfizer has an incentive to create a "bottleneck" with generic setraline production, and delay the clock for the 180 day exclusivity period for the first generic manufacturer, Ivax. Notably, DRL does not make any factual allegations showing that Pfizer has publicly commented or acted with regards to DRL's ANDA submission, other than a refusal to concede its legal rights with regards to the '699 patent.

By listing the '699 patent in the Orange Book, Pfizer has indicated that a future generic setraline product may infringe upon this patent. DRL argues that the submission of an ANDA itself creates a reasonable apprehension of litigation from the listed patent holder, citing for support a concurring opinion from the Federal Circuit on the issue. *See Minnesota Mining & Manufacturing Co. v. Mfg. Co. v. Barr Labs.*, 289 F.3d 775, 791 (Fed.Cir.2002) (Gajarsa, J., concurring).

However, the rationale of this opinion is based upon the fact

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that a patentee *could* reasonably assert a claim against a non-licensed manufacturer or marketer of the drug based upon the listing of the '699 patent in the Orange Book. In the absence of strong objective evidence "sufficient to indicate intent to initiate an enforcement action," the mere listing of multiple patents does not create declaratory judgment jurisdiction, especially in light of the fact that DRL cannot put its generic setraline to market until at least June 2006. *EMC Corp.* 89 F.3d at 811 (citation omitted). In fact, the objective evidence of Pfizer's intentions with regards to DRL's anticipated setraline product is that DRL has filed a paragraph IV certification with regards to the '699 patent, and Pfizer has not sued for infringement within the 45 day period provided by 21 U.S.C. § 355(j)(5)(B)(iii).[FN7] While the purpose of the Declaratory Judgment Act may be to prevent patent owners from brandishing the "sheathed sword" over the head of future competitors, the listing of patents in the Orange Book should not subject patent owners to defending non-infringement or invalidity without a chance to make a real investigation into whether the patent is actually infringed.[FN8]

FN7. While DRL may argue that Pfizer does not have an incentive to sue during this period because the thirty month stay created by the statute will expire before June 30, 2006, this was also the case with regards to the ANDA filed by IVAX. In that instance, Pfizer initiated litigation within that 45 day period.

FN8. Plaintiff DRL also cites *Hoechst Marion Roussel, Inc. v. Par Pharm.*, 39 U.S.P.Q.2d 1363 (D.N.J.1996) in support of the proposition that an ANDA filing automatically satisfies the requirement of a reasonable apprehension of suit. The opinion from this district deals with the issue as dicta in deciding whether a plaintiff seeking a declaratory judgement for non-infringement and invalidity would receive a jury trial under the Seventh Amendment. The opinion does not explain how such a requirement demonstrates conduct on the part of the patentee sufficient to show intent to initiate a patent infringement action.

*6 DRL has not alleged objective words or actions by Pfizer that demonstrate an intent to enforce its patent rights with regards to generic setraline either through explicit threats or "indirect threats or actions that place the declaratory plaintiff in reasonable apprehension of suit." *BP Chems.* 4 F.3d at 979. While DRL points to the listing of the '699 patent in the Orange Book as evidence, this occurred *before* DRL submitted the ANDA to the FDA for approval and the settlement of the lawsuit between DRL and IVAX regarding the '699 patent. The only action or communication regarding generic setraline between Pfizer and DRL was the refusal by Pfizer to give a convenant not to sue with regards to the '699 patent, which is not dispositive as to giving a reasonable apprehension of suit to the declaratory plaintiff. *See BP Chems.*, 4 F.3d at 980 (refusal to give assurances that the patentee will not enforce its patent is relevant but not dispositive).

Weighing all of the circumstances, Pfizer refusal to provide this covenant is perfectly reasonable in light of their need to make a fair investigation into DRL's representation that its setraline product would be a Form II polymorph not covered by the claims in the '699 patent.[FN9] Beyond Pfizer's need to investigate DRL's setraline product, DRL does not even have the ability to produce and market this product until June 2006. Therefore, Pfizer's refusal to give this covenant is not persuasive objective evidence that DRL has a reasonable apprehension of suit.

FN9. *See* June 9, 2003 Transcript of Oral Argument at 6; *see also American Needle & Novelty Co. v. Schuessler Knitting Mills, Inc.*, 379 F.2d 376, 379 (7th Cir.1967) ("The owner of a patent should have the privilege of making a fair investigation as to the possible infringement of his patent without calling down on his head the undertaking of a defense of an expensive and burdensome declaratory judgment suit alleging invalidity and non-infringement").

DRL also argues that Pfizer's decision to sue IVAX for infringement of the '699 patent in January 2000, after IVAX submitted an ANDA for a setraline product, provides an objective basis for a reasonable apprehension of suit.[FN10] While "[r]elated litigation may be evidence of a reasonable apprehension," *Shell Oil Co. v. Amoco Oil Co.*, 970 F.2d

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885, 888 (Fed.Cir.1992), the circumstances surrounding Pfizer's lawsuit against IVAX could suggest that Pfizer will not sue DRL regarding the '699 patent. Firstly, DRL argues in its own brief that Pfizer's interest is not to sue IVAX for infringement because a court decision might trigger the 180 day exclusivity period for the first generic entrant on the market (Pl's Opp. to Def's Mot to Dismiss at 23). While DRL seeks to demonstrate that Pfizer is waiting until the last possible moment in 2006 before suing for infringement of the '699 patent, it also tacitly concedes that DRL currently faces no reasonable apprehension of suit. Furthermore, the terms of the settlement between Pfizer and IVAX actually support the conclusion that Pfizer will not sue DRL with regards to the '699 patent. Because the settlement allows IVAX to begin marketing its generic setraline product at the end of the expiration of the "518 patent,[FN11] Pfizer has not been to able to delay the entry of a generic competitor through infringement litigation. Because the '699 patent was also at issue in that lawsuit, DRL cannot show that this related litigation was evidence of Pfizer's desire to delay the entry of generic competition through litigation.

FN10. *See* Ex. 3 to Pl's Opp. to Def's Mot to Dismiss.

FN11. The period of exclusivity was pushed back by six months to June 2006 by the FDA.

*7 Beyond this previous lawsuit, DRL also relies upon the alleged animosity of Pfizer executives and Pfizer's history of "aggressive assertion" of its patent rights against generic manufacturers. While DRL provides some quotations from Pfizer's CEO and other representatives about DRL, none of these remarks are directed towards DRL's attempts to produce a generic version of setraline. In the same regard, Pfizer's history of enforcing its patent rights does not provide any indication of Pfizer's intentions with regards to the '699 patent and DRL's generic setraline product. Neither argument demonstrates any evidence that DRL has an objective reasonable apprehension of suit by Pfizer. Furthermore, Pfizer failed to sue DRL within the statutory 45 day period after the paragraph IV certification for the '699 patent, thus providing some evidence that Pfizer does not intend to sue DRL.

All of the evidence listed by DRL that allegedly creates a reasonable apprehension of suit does not approximate "a level sufficient to indicate an intent [on the part of the patentee] to enforce its patent." *Shell Oil Co.*, 970 F.2d at 887. The only direct communication from Pfizer regarding the '699 patent and the DRL generic setralic product was simply a refusal to provide assurances that Pfizer would not sue. In weighing all of the circumstances, this refusal is entirely reasonable in light of the fact that Pfizer would need to have an adequate chance to investigate whether the generic product from DRL was truly a Form II polymorph. There is no rationale why the refusal to advise DRL three and a half years before its generic setraline product could possibly enter the market creates a reasonable apprehension that Pfizer will enforce its patent.[FN12] Weighing all of the circumstances, DRL has not fully persuaded this Court that there is a reasonable apprehension of litigation creating a case or controversy allowing this Court to exercise jurisdiction.

FN12. However, the circumstances may be altered dramatically if Pfizer still refuses to provide these assurances much closer to the potential market entry date of DRL's generic product. While this Court must find that there is an objectively reasonable apprehension of litigation, this fear could be established closer to the entry date in June 2006 by continued refusals of Pfizer to advise DRL whether it believes its generic setraline product infringes the '699 patent. Pfizer's continued silence on the issue may create an objectively reasonable fear on DRL's part that Pfizer is deliberately delaying infringement litigation in order to "sandbag" DRL at the last possible moment. The Court cannot predict the future with any confidence, however, and will not assume this scenario.

Finally, DRL argues that the unresolved issue of when the period of IVAX exclusivity will serves as an independent basis for this Court to exercise jurisdiction in order to resolve a "statutory bottleneck." (Pl's Opp. to Mot. to Dismiss at 24-25) Regardless of whether a statutory bottleneck is sufficient to create case or controversy jurisdiction, the purpose of resolving the triggering of the exclusivity period is

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to prevent the first ANDA filer from blocking subsequent generic entrants into the market because of "protracted litigation." *Minnesota Mining & Manuf. Co.*, 289 F.3d at 780. In this instance, the terms of the settlement agreement between IVAX and Pfizer make it clear that IVAX may begin marketing its generic setraline after the expiration of the '518 patent. Rather than Pfizer "manipulating the start date of IVAX exclusivity" (Pl's. Opp. At 24), DRL wishes to trigger the 180 day exclusivity period before IVAX begins to actually market its product, thus negating the benefits conferred upon the first generic entrant as an incentive to encourage generic producers of drugs. While claiming this is a "statutory bottleneck" preventing "full generic competition," DRL seeks to nullify the statutory benefit given as an incentive for generic companies who take the greatest risk of being the first generic entrant on the market. This argument is entirely unpersuasive as a basis for this Court to exercise jurisdiction.

V. Conclusion

***8** Defendant Pfizer seeks to dismiss DRL's action for declaratory judgment of non-infringement pursuant to 28 U.S.C. § 2201, the Declaratory Judgment Act. This Court is vested with "unique and substantial discretion in deciding whether to declare the rights of the litigants" under the Declaratory Judgment Act. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995). Because of the uncertainty whether DRL can truly demonstrate a reasonable apprehension of suit, and in order to allow Pfizer time to investigate a final form of DRL's product to ascertain whether it infringes upon the '699 patent, this Court exercises its discretion and declines to entertain this action under the Declaratory Judgment Act. The Court dismisses this complaint without prejudice. This case is closed.

D.N.J.,2003.
Dr. Reddy's Laboratories, Ltd. v. Pfizer, Inc.
Not Reported in F.Supp.2d, 2003 WL 21638254 (D.N.J.)

Briefs and Other Related Documents (Back to top)

• 2:03cv00726 (Docket) (Feb. 19, 2003)

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EXHIBIT H

Westlaw.

Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2004 WL 1465756 (D.Del.)
(Cite as: Not Reported in F.Supp.2d)

Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court,D. Delaware.

TORPHARM, INC., Apotex Corp. and Apotex, Inc., Plaintiffs,

v.

PFIZER INC. and Warner Lambert Company (n/k/a Warner-Lambert LLC) Defendants.

No. Civ.03-990-SLR.

June 28, 2004.

Steven J. Balick, John G. Day, Ashby & Geddes, Wilmington, Delaware, for Plaintiffs, William A. Rakoczy, Paul J. Molino, Deanne M. Mazzochi, Matthew O. Brady, Lord Bissell & Brook LLP, Chicago, Illinois, of counsel.

Jack B. Blumenfeld, James W. Parrett, Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware, for Defendants, Dimitrios T. Drivas, Jeffrey J. Oelke, Adam Gahtan, Brendan G. Woodard, White & Case LLP, New York, New York, of counsel.

MEMORANDUM OPINION

ROBINSON, Chief J.

I. INTRODUCTION

*1 On October 29, 2003, plaintiffs TorPharm, Inc., Apotex Corp., and Apotex, Inc. filed a declaratory judgment action against defendants Pfizer Inc. and Warner-Lambert Company. Plaintiffs seek a declaration that their generic version of Pfizer's patented drug Accupril® will not infringe U.S. Patent No. 4,743,450 ("the '450 patent"). (D.I.1) On February 23, 2004, plaintiffs filed an amended complaint to provide additional information about the statutory scheme for the approval of generic drugs. (D.I.18)

Plaintiff TorPharm is incorporated under the laws of Canada with its principal place of business in Etobicoke, Ontario, Canada. (D.I. 1 at ¶ 5) TorPharm develops, manufactures, and markets generic drugs, in particular solid oral dosage forms, such as capsules and tablets, for sale and use in the United States. (*Id.*) Plaintiff Apotex Corp. is incorporated under the laws of the State of Delaware with its principal place of business in Lincolnshire, Illinois. (D.I. 1 at ¶ 6) Apotex is the United States marketing and sales affiliate for TorPharm. (*Id.*) Plaintiff Apotex, Inc. is incorporated under the laws of Canada with its principal place of business in Weston, Ontario, Canada. (*Id.* at ¶ 7) Defendant Pfizer Inc. is organized under the laws of the State of Delaware with its principal place of business in New York, New York. (*Id.* at ¶ 9) Defendant Warner-Lambert LLC is a limited liability company organized under the laws of the State of Delaware with its principal place of business in Morris Plains, New Jersey.[FN1] (D.I. 1 at ¶ 10)

FN1. As of June 19, 2000, Warner-Lambert Company became a wholly owned subsidiary of defendant Pfizer Inc.. Warner-Lambert Company subsequently became Warner-Lambert LLC. (*Id.* at ¶ 10)

On January 8, 2004 and April 1, 2004, defendants filed motions to dismiss the complaint and the amended complaint, respectively, for lack of subject matter jurisdiction pursuant to Fed.R.Civ.P. 12(b)(1). (D.I.8, 20) These motions are presently before the court. For the reasons to follow, the court grants both motions.

II. BACKGROUND

A. Regulatory Approval for Brand Drugs

Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), an innovator pharmaceutical company ("innovator") who seeks to manufacture a new brand drug is required to file a new drug application ("NDA") with the Federal Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). Submitting an NDA is frequently a time-intensive and costly process because, among other things, the NDA must contain detailed clinical studies of the brand drug's safety and efficacy. The NDA also must include a list of patents which claim the brand drug:

The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be

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asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.... Upon approval of the application, the Secretary shall publish information submitted under [this section].

*2 21 U.S.C. § 355(b)(1). If the FDA approves an NDA, then it publishes, or "lists," information about the brand drug and patents covering the brand drug's approved aspects in a publication called "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." *Id.*

B. Regulatory Approval for Generic Drugs

Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§ 156, 271, 282,[FN2] a generic drug manufacturer ("generic") who seeks approval to market a generic version of a previously approved brand drug may submit an abbreviated new drug application ("ANDA") to the FDA.[FN3] 21 U.S.C. § 355(j). In the ANDA, a generic may rely on the safety and efficacy studies previously submitted to the FDA in the innovator's NDA by showing the generic drug's bioequivalence with the previously approved brand drug. 21 U.S.C. § 355(j)(2)(A). The generic also must "certify" whether the generic drug would infringe the patent(s) listed in the Orange Book for the brand drug. 21 U.S.C. § 35(j)(2)(A)(vii). To satisfy this requirement, a generic may make one of four possible certifications for each patent claiming either the listed brand drug or the use of the listed brand drug: (I) that no patent information on the brand drug has been submitted to the FDA; (II) that the listed patent has expired; (III) that the listed patent will expire on a stated date; or (IV) that the listed patent is invalid or will not be infringed by the generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). These options are designated as paragraph I, II, III, and IV certifications, respectively.

> FN2. The Drug Price Competition and Patent Term Restoration Act of 1984 is more commonly known as the "Hatch-Waxman Act." It amended various provisions of the FFDCA and Title 35 of the United States Code relating to patents. Title I of the Act was intended to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1326 (Fed.Cir.2001) (citing H.R.Rep. No. 98-857, pt. 1 at 14 (1984)).
>
> FN3. A generic does not commit an act of infringement in submitting an ANDA. 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell ... a patented invention ... solely for uses reasonably related to the development and submission of information under a[f]ederal law which regulates the manufacture, use, or sale of drugs.").

With a paragraph I or II certification, the FDA may grant approval as soon as it is satisfied that the product is safe and effective. 21 U.S.C. § 355(j)(5)(B)(i). Under a paragraph III certification, the FDA may approve the ANDA as soon as the patent on the brand drug expires. 21 U.S.C. 355(j)(5)(B)(ii). If the generic enters paragraph III certifications for more than one patent, then the FDA may not grant approval until the last patent expires. Filing an ANDA with a paragraph IV certification presents a more unique situation; it is considered to be a "technical" or "artificial" act of infringement. 21 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit an application under section 505(j) of the [FFDCA] or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent."); *see Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) ("[A]n act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by § 271(e)(2)-the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent."). Consequently, the ANDA applicant must explain why a generic version of the previously approved brand drug would not infringe the patent covering the previously approved brand drug or why such patent is invalid. 21 U.S.C. § 355(j)(2)(B)(i). In response, the patent holder has the option of filing a patent infringement action within

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forty-five days after receiving such notice. 21 U.S.C. § 355(j)(5)(B)(iii). During this window, the generic may not file a declaratory judgment action based upon the filing of the ANDA. *Id.* If the patent holder fails to bring suit, then the FDA may approve the ANDA. *Id.* However, if the patent holder elects to bring suit, then the effective date of any FDA approval is delayed for either thirty months or until a court rules that the patent is invalid or not infringed, whichever occurs first. *Id.*

*3 The first generic to file an ANDA containing a paragraph IV certification is known as a "first filer" and is eligible for a 180-day exclusivity period. This means that the first filer is entitled to have the sole generic version of the brand drug on the market for the first 180-days following the earlier of: (1) the date of the first commercial marketing of the generic drug by the first filer; or (2) a court decision of noninfringement or invalidity by any ANDA applicant in any action. 21 U.S.C. § 355(j)(5)(B)(iv). Any subsequent ANDA filer must wait until the expiration of this 180-day exclusivity period before the FDA will approve its ANDA.[FN4]

FN4. If the first filer does not opt to commercially market its generic drug, then subsequent ANDA filers may trigger the 180-day exclusivity period by obtaining a court decision of noninfringement or invalidity.

B. The Medicare Act

On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, § 1102(a), 117 Stat.2066, 2457-60 (the "Medicare Act"). (D.I. 18 at ¶ 48) Title XI of the Act, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA. (*Id.*) In particular, the Medicare Act amended 21 U.S.C. § 355(j)(5)(C)(i)(I)(2) to provide that a generic who has filed a paragraph IV certification may bring a declaratory judgment action against the patent holder and/or holder of the NDA if: (1) the forty-five day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the holder of the NDA brought an action for patent infringement within the forty-five day period; and (3) the patent owner and holder of the NDA have been granted an offer of confidential access to the ANDA. The Medicare Act also amended 21 U.S.C. § 355(j)(5)(C)(i)(II) to provide that if the above three conditions are satisfied, then

> the applicant ... may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the [patent] owner or holder [of the NDA] ... for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval.

The Medicare Act likewise added a new provision to 35 U.S.C. § 271(e), the section of the patent code relevant to infringement actions. This provision provides that if: (1) a generic makes a paragraph IV certification; and (2) the patent holder or holder of the NDA fails to sue the generic for patent infringement within the forty-five day window after receiving notice; then (3) "the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5) (emphasis added).

C. The Brand Drug Product

Accupril® is the brand name for *quinapril hydrochloride*. The FDA has approved Accupril® for the treatment of hypertension and for the management of heart failure. (D.I. 21 at ¶ 4) Accupril® has been on the market in the United States since 1991. (*Id.*) In accordance with 21 U.S.C. § 355(b)(1), Pfizer listed the numbers and the expiration dates for the patents covering either Accupril® tablets or a method of using those tables with the FDA. (*Id.*) The FDA, in turn, published this information in the Orange Book. (*Id.*) The '450 patent is one of the patents found in the Orange Book; it expires on February 24, 2007. (*Id.*)

D. The First Filer

*4 At a date prior to January 15, 1999, Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with paragraph IV certification directed to *quinapril hydrochloride*. (D.I. 22 at ¶ 2) Teva asserted that the '450 patent is invalid.[FN5] On January 15, 1999, Teva notified defendant Warner-Lambert of this filing. (*Id.*) Within forty-five days thereafter, defend-

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ant Warner-Lambert filed an action against Teva for infringement of the '450 patent in the United States District Court for the District of New Jersey. (*Id.* at ¶ 4; D.I. 26 at 11) On October 2, 2003, the District of New Jersey held that Teva infringes the '450 patent and granted summary judgment in favor of Pfizer on this ground. *See Warner-Lambert Co. v. Teva Pharms. USA*, 289 F.Supp.2d 515, 545 (D.N.J.2003).[FN6] The parties have yet to litigate the issues of validity and enforceability. (D.I. 22 at ¶ 5)

FN5. The FDA approved Teva's ANDA on May 30, 2003. (D.I. 21 at 7)

FN6. After receiving this favorable decision, defendants issued a press release commenting on the ruling. Defendants' senior vice president and general counsel stated: "[Defendants] [are] pleased with the court's summary judgment decision because it affirms positions the company has maintained with respect to the Accupril® patent from the very beginning of the litigation.... [Defendants] will continue aggressively to defend challenges to its intellectual property." (D.I.21, ex. D)

As the first filer, Teva is entitled to a 180-day period of generic exclusivity from the earlier of: (1) the date it first commercially markets generic *quinapril hydrochloride*; or (2) the date of a court decision declaring the '450 patent invalid. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I), (II). To date, neither event has occurred. If Teva prevails in its litigation against Warner-Lambert and the District of New Jersey declares the '450 patent invalid, then the clock will start running on Teva's 180-day exclusivity period. Other generics who receive FDA approval will be able to begin marketing their generic versions of *quinapril hydrochloride* upon expiration of Teva's period of exclusivity.

E. Plaintiffs' ANDA

On September 13, 2001, plaintiffs filed an ANDA seeking approval to market its own generic version of *quinapril hydrochloride*. (D.I. 18 at ¶ 62) Plaintiffs entered a paragraph IV certification with respect to the '450 patent. (*Id.* at ¶ 64) Around November 15, 2001, plaintiffs notified defendants about the ANDA filing and the paragraph IV certification pursuant to 21 U.S.C. 355(j)(2)(B)(iv). (*Id.* at ¶ 67) Defendants did not file a patent infringement action asserting the '450 patent against plaintiffs within forty-five days of receiving this notice. (D.I. 22 at ¶ 6) On February 3, 2004, plaintiffs sent a letter to defendants offering confidential access to their ANDA. (D.I. 18 at ¶ 69; D.I. 21, ex. G)

F. Other ANDAs Directed to *Quinapril Hydrochloride*

Besides Teva and the plaintiffs at bar, eight other generics have filed ANDAs seeking approval to market generic *quinapril hydrochloride* between January 2001 and May 2003.[FN7] These generics include: (1) Geneva Pharmaceuticals, Inc; (2) Andrx Pharmaceuticals, Inc.; (3) Par Pharmaceuticals, Inc.; (4) Ivax Pharmaceuticals, Inc.; (5) Mutual Pharmaceutical Company, Inc.; (6) Ranbaxy Pharmaceuticals Inc.; (7) Amide Pharmaceutical, Inc.; and (8) Mylan Pharmaceuticals Inc.. (D.I. 22 at ¶ 7) Pfizer has not initiated litigation against any of these eight companies in connection with their ANDAs. (*Id.*)

FN7. Though not specifically stated by the parties, the court presumes that each of these generics included paragraph IV certifications in their ANDA filings based upon the parties' representations about these filings.

III. STANDARD OF REVIEW

*5 "Federal courts are courts of limited jurisdiction. They possess only that power authorized by the Constitution and statute.... It is to be presumed that a cause lies outside this limited jurisdiction and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Kokkonen v. Guardian Life Ins. Co. Of Am.*, 511 U.S. 375, 377 (1994) (citations omitted). A subject matter jurisdiction attack under Fed. R. Civ. Pro. 12(b)(1), therefore, challenges the court's jurisdiction to address the merits of the complaint. *See Lieberman v. Delaware*, 2001 WL 1000936, at *1 (D.Del.2001). A party may raise the lack of subject matter jurisdiction at any time; it cannot be waived. Fed.R.Civ.P. 12(h)(3). In fact, the court is obliged to address the issue on its own motion, if not raised by the parties. *See Neiderhiser v. Berwick*, 840 F.2d 213, 216 (3d Cir.1988). Once jurisdiction is challenged, the party asserting subject matter juris-

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diction has the burden of proving its existence. *See* *Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 69 (3d Cir.2000).

Under Rule 12(b)(1), the court's jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). *Mortensen v. First Fed. Sav. & Loan*, 549 F.2d 884, 891 (3d Cir.1977). Under a facial challenge, the court must accept as true the allegations contained in the complaint. *See* 2 James W. Moore, Moore's Federal Practice § 12.30[4] (3d ed.1997). Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or ... is wholly insubstantial and frivolous.' " *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408-1409 (3d Cir.1991) (quoting *Bell v. Hood*, 327 U.S. 678, 682 (1946)).

Under a factual attack, however, the court is not "confined to allegations in the ... complaint, but [may] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir.1997); *see also* *Mortensen*, 549 F.2d at 891-892. "No presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Carpet Group*, 227 F.3d at 69 (quoting *Mortensen*, 549 F.2d at 891). Because defendants did not answer either plaintiffs' original complaint or their amended complaint, the court shall treat the instant subject matter jurisdiction challenge as a facial attack.

IV. DISCUSSION

A. The Legal Standard for Declaratory Judgment

The Declaratory Judgment Act states in pertinent part:
In a case of actual controversy within its jurisdiction, ... any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

*6 28 U.S.C. § 2201(a). Under this act, a court may declare the rights and other legal relations of any interested party only where there exists an "actual controversy." *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed.Cir.1999). This requirement effectuates Article III of the Constitution, which authorizes the federal judiciary to hear justiciable cases and controversies.[FN8] *See* *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed.Cir.1996).

> FN8. The Supreme Court has held that Article III is satisfied where there is: (1) an actual or imminent injury-in-fact; (2) that is fairly traceable to the defendant; and (3) is redressible by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992).

To guide the case-or-controversy analysis in patent-based declaratory judgment suits, the Federal Circuit has developed a two-part test. "For actual controversy to exist, '[t]here must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit; and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.' " *Amana*, 172 F.3d at 855 (quoting *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed.Cir.1993)). The burden is on the declaratory judgment plaintiff "to establish that jurisdiction over its declaratory judgment action existed at, and has continued since, the time the complaint was filed." *Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc.*, 787 F.2d 572, 575 (Fed.Cir.1986). "Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction." *EMC Corp.*, 89 F.3d at 810.

The first prong looks to the patent holder's conduct. *BP Chems. Ltd.*, 4 F.3d at 978. If a defendant expressly charges that a plaintiff's current activity constitutes infringement, then there is an actual controversy. *Arrowhead Indus. Water v. Ecolochem*, 846 F.2d 731, 736 (Fed.Cir.1988). In light of the subtleties in lawyer language, however, courts have not required an express infringement charge. *Id.* (citing *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed.Cir.1987)). When the defendant's conduct, in-

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cluding its statements, falls short of an express charge, the court must consider the "totality of the circumstances" in determining whether the defendant's conduct meets the first prong of the test. *Arrowhead*, 846 F.2d at 736. Thus, the declaratory judgment plaintiff must demonstrate "conduct that rises to a level sufficient to indicate an intent [of the patent holder] to enforce its patent, i.e., to initiate an infringement action." *EMC Corp.*, 89 F.3d at 811 (citations omitted). Subjective impressions of the declaratory judgment plaintiff, however, are insufficient to satisfy the requirement. The court must find objective facts considering the totality of the circumstances at the time the complaint was filed. *Arrowhead*, 846 F.2d at 736.

The second prong looks to the potential infringer's conduct. *BP Chems. Ltd.*, 4 F.3d at 978. The potential infringer must be engaged in an actual making, selling, or using activity subject to an infringement charge or must have made meaningful preparation for such activity. This prong insures that the declaratory judgment plaintiff has a "true interest to be protected" and prevents such plaintiff from seeking an advisory opinion on potential liability for initiating some future activity. *Arrowhead*, 846 F.2d at 736.

B. Defendants' Motion to Dismiss

1. Subject Matter Jurisdiction Pursuant to the Medicare Act

*7 Plaintiffs argue that they are not required to satisfy the reasonable apprehension of suit requirement to confer subject matter jurisdiction pursuant to the amendments made to 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5) by the Medicare Act. (D.I. 26 at 14) Plaintiffs claim that they need only satisfy the case or controversy requirement of Article III of the Constitution. In this regard, plaintiffs contend that they have been directly injured by defendants because they cannot enter the *quinapril hydrochloride* market with their generic product until after the '450 patent expires due to the "bottleneck" that defendants created by engaging in litigation against Teva.[FN9] Plaintiffs maintain that a declaratory judgment in their favor will redress this injury as they will be able to market their generic version of *quinapril hydrochloride*. Accordingly, plaintiffs aver that the court has subject matter jurisdiction over the instant dispute.

FN9. Recall that pursuant to 21 U.S.C. 355(j)(5)(B)(iv), the FDA cannot approve plaintiffs' ANDA until 180 days after Teva enters the market with its generic *quinapril hydrochloride* or until a favorable court decision on the '450 patent, whichever is earlier. Plaintiffs claim that Teva will not enter the market because the District of New Jersey found that its generic version of *quinapril hydrochloride* infringed the '450 patent. Plaintiffs also allege that defendants have delayed filing suit against them or any of the other subsequent ANDA filers to avoid triggering a court decision that potentially may find the '450 patent not infringed or invalid

The court does not read the plain language of either 21 U.S.C. § 355(j)(5)(C)(i)(II) or 35 U.S.C. § 271(e)(5) as eliminating the Federal Circuit's two-part test. Rather, the plain language of 21 U.S.C. § 355(j)(5)(C)(i)(II) requires a generic to satisfy three prerequisites before lodging a declaratory judgment action against a patent holder; this provision does not in any way address subject matter jurisdiction. The plain language of 35 U.S.C. § 271(e)(5), on the other hand, reaches the issue of subject matter jurisdiction. It requires courts to exercise subject matter jurisdiction in a patent-related declaratory judgment action "consistent with the Constitution." The court interprets this language to mean that a generic must satisfy the case and controversy requirement set forth in Article III. Given that the Federal Circuit established its two-part test to guide the case-or-controversy analysis in conformity with Article III, the court finds that this test is "consistent with the Constitution" and applicable to the litigation at bar.

The court observes that the legislative history for the Medicare Act substantiates this interpretation. Congress specifically contemplated a continuation of the constitutional standard for subject matter jurisdiction, including the reasonable apprehension requirement. According to the House of Representatives conference report,

[t]he conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effect to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to

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apply the 'reasonable apprehension' test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III. Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a 'reasonable apprehension' of suit to establish jurisdiction. The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act. In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the [forty-five] days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

*8 H.R. Conf. Rep. No. 108-391, at 836 (2003) (citations omitted) (emphasis added). Taking this explanation together with the Federal Circuit's plain language of the Medicare Act, the court concludes that the two-part test remains as the standard for determining whether a district court has subject matter jurisdiction over a patent-based declaratory judgment action.

Turning to the facts at bar, plaintiffs were not required to comply with the three prerequisites set forth in 21 U.S.C. § 355(j)(5)(C)(i)(II) because they filed their original complaint on October 29, 2003, approximately one month prior to the enactment of the Medicare Act on December 8, 2003. Nevertheless, the Medicare Act applies to all proceedings pending on or after December 8, 2003. As such, defendants focus on plaintiffs' amended complaint, which was filed on February 23, 2004, nearly three months after the Medicare Act became effective. To this end, defendants argue that plaintiffs filed their amended complaint only twenty days after offering defendants confidential access to their ANDA, well within the forty-five day period.

At the outset, the court observes that defendants confuse the prerequisites. The Medicare Act states that a declaratory judgment action may not be brought unless: (1) the forty-five day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor holder of the NDA brought an action for infringement of the patent within the forty-five day period; and (3) the patent owner and holder of the NDA have been granted an offer of confidential access to the ANDA. The forty-five day window, therefore, relates to notice of the ANDA filing containing the paragraph IV certification, not notice of the complaint or, in the case at bar, the amended complaint. Additionally, compliance with the Medicare Act as of the date of the amended complaint is of no import; the Medicare Act seeks to ensure that a patent holder has full opportunity to consider an ANDA and decide whether to file an infringement action prior to being forced to stand in defense in a declaratory judgment action. This consideration occurs with the filing of an original complaint, not as of the filing of an amended complaint in a suit already in progress. Accordingly, the court declines to dismiss the instant litigation on procedural grounds.

2. Subject Matter Jurisdiction Under the Federal Circuit's Two-Part Test [FN10]

> FN10. The parties dispute only the first prong of this test, to wit, whether plaintiffs were in reasonable apprehension of an infringement suit as of October 29, 2003, the date of plaintiffs' original complaint. The court, therefore, confines its analysis to this question. For sake of clarity, the court observes that plaintiffs satisfied the second prong of the two-part test, i.e., activity which could constitute infringement, by filing the ANDA. *See* 35 U.S.C. § 271(e)(2); *see also infra* Section II, A.

Plaintiffs argue that they were under a reasonable apprehension of suit at the time they filed their complaint based upon various actions by defendants, including the following: (1) listing the '450 patent in the Orange Book [FN11] (D.I. 18 at ¶¶ 27, 89); (2) failing to state that plaintiffs' generic version of *quinapril hydrochloride* does not infringe the '450 patent or to provide plaintiffs with a covenant not to sue (*id.* at ¶ 89); (3) initiating an infringement lawsuit against Teva regarding the '450 patent (*id.* at ¶¶ 80, 81); (4) stating in a press release "that it will continue to aggressively defend challenges to its intellectual property" (*id.* at ¶¶ 79, 89; D.I.

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21, ex. D); and (5) initiating a lawsuit against plaintiffs over a different product (Neurotin®), thereby showing a "pattern of aggressively enforcing its patents" against "the generic pharmaceutical industry generally." (*Id.* at ¶¶ 72-78, 89)

> FN11. Plaintiffs argue that defendants implied that an infringement action could be brought against any generic who seeks ANDA approval for a generic version of *quinapril hydrochloride* by listing the '450 patent in the Orange Book.

*9 Before delving into the details of plaintiffs' arguments, the court recognizes that it is often difficult to identify whether a reasonable apprehension of suit exists. This question entails a balance, similar to the balance that the Hatch-Waxman Act struck between innovators and generics. On the one hand, a patent owner should not be dragged into court when it has not engaged in threatening or aggressive acts simply because it chooses to inform potential infringers of its patent rights. In the case of the pharmaceutical industry, an innovator has invested a tremendous amount of research effort, dollars, and time into developing and marketing a brand drug. Such innovators also have expended considerable resources in establishing a patent portfolio to protect said brand drug. The court respects both the innovator's efforts and legitimate patent rights and does not easily dismiss these investments. On the other hand, however, the Declaratory Judgment Act was enacted to prevent patent owners from using "guerrilla-like" tactics and attempting "extrajudicial patent enforcement with scare-the-customer-and-run tactics that infect the competitive environment of the business community with uncertainty and insecurity." *Arrowhead*, 846 F.2d at 735. As well, the court is mindful that a generic should be entitled to market its generic version of a brand drug if a product does not infringe the patent listed in the Orange Book for the brand drug or said patent is invalid. In such situations, the court appreciates that a declaratory judgment action may be the only means for a generic to reach the market given the possibility for a so-called "bottleneck."

With this background in mind, the court turns to consider plaintiffs' contentions concerning the first prong of the two-part test. Plaintiffs argue that a generic, in general, is placed in a position of reasonable apprehension of litigation when it submits an ANDA because a patent holder may file a patent infringement action against it.[FN12] In asserting this position, plaintiffs reference the concurrence from Judge Gajarsa in *Minnesota Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775 (Fed.Cir.2002). Judge Gajarsa opined that

> FN12. Recall that in listing a patent in the Orange Book, a patent holder represents that a claim for infringement "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale" of the drug. *See* 21 U.S.C. § 355(b)(1).

> filing an NDA application meets prong one of the declaratory judgment case or controversy requirement, because filing the application requires the patentee to maintain that an infringement suit could 'reasonably be asserted' against one who 'engaged in the manufacture, use or sale of the drug.' This is 'conduct giving rise to a reasonable apprehension on the plaintiff's part that it will face an infringement suit or the threat of one.'
> *Id.* at 791 (citations omitted).[FN13]

> FN13. Similarly, the D.C. Circuit appears to share this view, stating that
> [t]he Federal Circuit has had no occasion to decide whether there is a 'controversy of sufficient immediacy and reality' to support a declaratory judgment action, ... when the plaintiff requires a judgment under section 355(j)(5)(B) in order to bring its product to market. It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a 'case or controversy' without demonstrating an immediate risk of being sued.
> *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 n. 18 (D.C.Cir.1998).

Judge Gajarsa's reasoning addresses the practical difficulties facing a generic in plaintiffs' situation, i.e., a generic who does not face a "reasonable apprehension of suit" but who needs a judicial determination in order to get to market. Nevertheless, absent binding precedent or further edification

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through legislation, the court declines to extend the well established principles governing declaratory judgment actions to cover the admittedly frustrating position occupied by plaintiffs at bar. In the first instance, defendants were required by statute to list the '450 patent in the Orange Book. In light of this obligation, the court is not convinced that defendants intended to communicate an intent to sue each and every generic who opts to file an ANDA for *quinapril hydrochloride*, contrary to plaintiffs' suggestion. The evidence of record, in fact, shows an opposite intention. To date, defendants have asserted the '450 patent only against Teva, despite at least eight other generics having filed ANDAs for *quinapril hydrochloride* with paragraph IV certifications. Additionally, our sister courts, when confronted with virtually identical facts to those at bar, have found that the act of listing a patent in the Orange Book does not create an "actual controversy." *See Mutual Pharm. v. Pfizer*, 307 F.Supp.2d 88 (D.D.C.2004); *Dr Reddy's Labs, Ltd v. Pfizer Inc.*, 2004 WL 596106 (D.N.J.2003); *Teva Pharm. USA Inc. v. Pfizer Inc.*, 69 U.S.P.Q.2d 1791 (D.Mass.2003). Indeed, the District of Massachusetts has noted that "[a] blanket reference to this effect would cover every patent holder who listed a patent, thereby eliminating the second prong of the test. A patent holder may have reasons to sue for infringement, and all things depending, reasons not to sue." *Id* at *13. The court, consequently, concludes that the mere listing of a patent in the Orange Book does not give plaintiffs reason to fear suit.

***10** Plaintiffs also point out that defendants failed to state that plaintiffs' generic version of *quinapril hydrochloride* does not infringe the '450 patent and failed to provide them with a covenant not to sue. While the Federal Circuit previously has acknowledged that a patent holder's failure to give such an assurance is relevant to a court's jurisdictional inquiry, *BP Chems. Ltd.* 4 F.3d at 980, plaintiffs fail to cite evidence to demonstrate that they requested either an assurance or a covenant not to sue. Moreover, even if plaintiffs made such requests, defendants are not required under the Hatch-Waxman Act to give either an assurance or a covenant not to sue. Thus, the court declines to construe defendants' silence as conduct sufficient to suggest an intention to sue.

Plaintiffs likewise maintain that defendants' litigation history establishes a reasonable apprehension of suit. In this regard, plaintiffs call attention to fact that defendants: (1) are engaged in an ongoing infringement action against Teva regarding the '450 patent; (2) have been involved in suits against plaintiffs and at least eight other ANDA filers over Neurotin® for the past five years; and (3) are actively pursuing other infringement actions against various generics who sought to market generic versions of their brand drugs, including Zoloft®, Celebrex®, Lipitor®, Norvasc®, Procardia XL®, Glucotrol XL®, and Xalatan®. As to plaintiffs' litigation involving the '450 patent, defendants have not sued any of the subsequent eight ANDA filers, four of whom filed ANDAs prior to plaintiffs.[FN14] Contrary to plaintiffs' characterization of this fact as "meaningless," the court finds it to be persuasive evidence that defendants are not engaged in a pattern of widespread litigation aimed at enforcing the '450 patent against all generics interested in marketing generic *quinapril hydrochloride* As such, the court declines to conclude that defendants' litigation efforts with respect to Teva translate into an intent to enforce the '450 patent against plaintiffs.

> FN14. Geneva Pharmaceuticals, Andrx Pharmaceuticals, Par Pharmaceuticals, Inc., and Ivax Pharmaceuticals, Inc. filed ANDAs seeking approval to market generic *quinapril hydrochloride* on January 9, 2001, January 25, 2001, June 1, 2001, and July 20, 2001, respectively. Plaintiffs did not file their ANDA until September 13, 2001.

The court is equally unpersuaded that defendants' Neurotin® litigation created a reasonable apprehension of suit. In *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed.Cir.1987), the Federal Circuit acknowledged that a history of adverse legal interests bears upon the reasonable apprehension issue, even if the prior litigation did not involve the same patents implicated in the declaratory judgment suit. Nonetheless, the court observes that the link between the parties' adverse legal interests in *Goodyear* were much stronger than those at bar. In *Goodyear*, the defendant sued the plaintiff in state court over the same technology covered by the patents disputed in the declaratory judgment action. The Federal Circuit opined that, "[b]y su-

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ing Goodyear in state court for the same technology as is now covered by the patents, [defendant] has engaged in a course of conduct that shows a willingness to protect that technology." *Id.* at 956. In contrast, defendants' Neurotin® litigation does not implicate the same technology as would be involved in a suit over Accupril®. Therefore, the court finds that defendants' desire to protect their presence in the pain and seizure markets with Neurotin® is unrelated to their intentions as to the hypertension and heart failure markets with Accupril®. While the parties' adverse interests remain a consideration, the court finds that the factual background in this case, unlike the factual background in *Goodyear*, is not such that plaintiffs had an objective reason to fear litigation.

*11 Similarly, the court finds that defendants' litigation against third party generics, even when viewed in the aggregate with defendants' suit against Teva and their Neurotin® litigation, does not place plaintiffs in a reasonable apprehension of suit. (*See* D.I. 27, ex. B) Plaintiffs overdramatize the situation in stating "there is no end to the lengths that [defendants] will go to protect its branded monopolies through litigation." Plaintiffs' subjective beliefs do not amount to a threat or other action sufficient to prove the imminence of a lawsuit. In addition, that defendants enforced their patent rights against other generics with respect to Zoloft®, Celebrex®, Lipitor®, Norvasc®, Procardia XL®, Glucotrol XL®, and Xalatan® does not provide any indication of its intentions regarding the '450 patent and *quinapril hydrochloride*. To this end, the Federal Circuit considers whether the parties have engaged in some form of communication about the patent in dispute when analyzing the reasonable apprehension question.[FN15] The Federal Circuit has cautioned:

> FN15. Notably, the Federal Circuit also has recognized that "[i]f circumstances warrant, a reasonable apprehension may be found in the absence of any communication from defendant to plaintiff." *Arrowhead*, 846 F.2d at 736.

The test for finding a "controversy" for jurisdictional purposes is a pragmatic one and cannot turn on whether the parties use polite terms in dealing with one another or engage in more bellicose saber rattling. The need to look to substance rather than form is especially important in this area, because in many instances ... the parties are sensitive to the prospect of a declaratory judgment action and couch their exchanges in terms designed either to create or defeat declaratory judgment jurisdiction. In the end, the question is whether the relationship between the parties can be considered a "controversy," and that inquiry does not turn on whether the parties have used particular "magic words" in communicating with one another.

EMC Corp., 89 F.3d at 811-12. The Federal Circuit has found no apprehension of suit existed where the patent holder has made no contact with the declaratory judgment plaintiff. *West Interactive Corp. v. First Data Res., Inc.*, 972 F.2d 1295, 1297 (Fed.Cir.1992).[FN16] In the case at bar, plaintiffs have not alleged any communication, either direct or indirect, from defendants concerning the '450 patent. The record also does not reveal any such communication. Moreover, the record does not show that defendants communicated with any third parties about plaintiffs or the '450 patent. As noted above, defendants have stood silent throughout the course of this litigation. The only interaction between the parties, in fact, occurred when plaintiffs initiated contact with defendants by: (1) notifying them of their ANDA with paragraph IV certification as required by 21 U.S.C. § 355(j)(2)(B); and (2) sending them a letter offering confidential access to their ANDA in accordance with 35 U.S.C. § 355(j)(5)(C)(i)(I)(2). Given these circumstances, plaintiffs cannot complain that they feared that defendants would sue them for patent infringement.

> FN16. In contrast, the Federal Circuit has held the reasonable apprehension inquiry satisfied in certain situations where the defendant directly communicated with the plaintiff. *See, e.g., Sierra Applied Scis., Inc. v. Advanced Energy Indus.*, 363 F.3d 1361, 1374 (Fed.Cir.2004) (concluding that letters from defendant to plaintiff expressly charging plaintiff with patent infringement were sufficient to establish a reasonable apprehension); *EMC Corp.*, 89 F.3d at 812 (finding a letter from defendant to plaintiff referencing " 'turn[ing] the matter over to" ' plaintiff's litigation counsel " 'for action" ' and urging a " 'preliminary business discussion," ' " 'perhaps avoiding this matter escalating into a con-

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tentious legal activity[,]" ' to be the "most telling evidence" of reasonable apprehension).

*12 Finally, defendants' press release statement that they "will continue aggressively to defend challenges to [their] intellectual property" is not sufficient to instill a reasonable apprehension of suit. Defendants' statement, even though made in the context of discussing the infringement suit against Teva, is of a general nature, directed to their overall strategy of enforcing their patent rights against generic competition. It is not specifically directed against plaintiffs, nor is there any evidence suggesting that it was made with plaintiffs in mind. The Federal Circuit has held that a patent holder's statement that it intends to enforce its patent does not create a reasonable apprehension of suit. *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051, 1054 (Fed.Cir.1995) (discussing *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 889 (Fed.Cir.1992)). Accordingly, the court concludes that, under the totality of the circumstances, defendants did not engage in conduct sufficient to give plaintiffs a reasonable apprehension of suit at the time they filed the complaint at bar. The court, therefore, grants defendants' motions to dismiss for lack of subject matter jurisdiction. FN17

FN17. As noted above, the court is sympathetic to plaintiffs' situation. Plaintiffs must dwell within the frustrating Hatch-Waxman "bottleneck" (the expiration of Teva's 180-day period of exclusivity) before marketing their generic version of *quinapril hydrochloride*. The start of this exclusivity period presently, however, remains unknown and will not be triggered until either: (1) Teva voluntarily markets its generic *quinapril hydrochloride*, which it is not likely to do given the District of New Jersey's finding of infringement; (2) the District of New Jersey decides the issues of validity and enforceability of the '450 patent; or (3) another court declares the '450 patent invalid. Thus, subsequent ANDA filers, like plaintiffs, are placed in a conundrum when attempting to market their generic versions of brand drugs under the current regulatory framework.

V. CONCLUSION

For the reasons stated, the court grants defendants' motions to dismiss for lack of subject matter jurisdiction. An order shall issue.

ORDER

At Wilmington this 28th day of June, 2004, consistent with the opinion issued this same date;

IT IS ORDERED that defendants' motions to dismiss (D.I.8, 20) are granted.

D.Del.,2004.
Torpharm, Inc. v. Pfizer, Inc.
Not Reported in F.Supp.2d, 2004 WL 1465756 (D.Del.)

Briefs and Other Related Documents (Back to top)

• 1:03cv00990 (Docket) (Oct. 29, 2003)

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EXHIBIT I

PREPARED STATEMENT OF THE FEDERAL TRADE COMMISSION

Before the

SPECIAL COMMITTEE ON AGING

of the

UNITED STATES SENATE

on

BARRIERS TO GENERIC ENTRY

July 20, 2006

Chairman Smith, Ranking Member Kohl, and Members of the Committee, I am Jon Leibowitz, Commissioner of the Federal Trade Commission ("FTC" or "Commission"). I am pleased to appear before you today to testify on behalf of the Commission regarding barriers to generic entry in the pharmaceutical industry.[1]

Advances in the pharmaceutical industry continue to bring enormous benefits to Americans. Because of pharmaceutical innovations, a growing number of medical conditions often can be treated more effectively with drugs and drug therapy than with alternative means (*e.g.*, surgery). The development of new drugs is risky and costly, however.

At the same time, the escalating cost of health care in the United States – and in particular, of prescription drugs – is an enormous, nationwide problem. As the Government Accountability Office reported last year: "Prescription drug spending as a share of national health expenditures increased from 5.8 percent in 1993 to 10.7 percent in 2003 and was the fastest growing segment of health care expenditures."[2] Older Americans, typically those in greatest need of health care in our population and often living on fixed incomes, bear a disproportionate share of these costs. Although people over 65 are only 13 percent of the population, they account for 42 percent of all drug expenditures.[3] Pharmaceutical expenditures are a concern not only to individual consumers, but also to government payers, private health plans, and employers. Generic drugs play an important role in containing rising prescription drug costs, by offering consumers therapeutically identical alternatives to brand-name drugs, at a significantly reduced cost.

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[1] This written statement represents the views of the Federal Trade Commission. My oral presentation and responses are my own and do not necessarily reflect the views of the Commission or of any Commissioner.

[2] Government Accountability Office, *PRESCRIPTION DRUGS: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004* at 1 (Aug. 2005).

[3] Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly*, 1992-2010 at 2, 13 (July 2000).

To address the issue of escalating drug expenditures, and to ensure that the benefits of pharmaceutical innovation would continue, Congress passed the Hatch-Waxman Amendments[4] ("Hatch-Waxman" or "the Amendments") to the Food, Drug and Cosmetic Act ("FDC Act") in 1984.[5] Hatch-Waxman established a regulatory framework that sought to balance incentives for continued innovation by research-based pharmaceutical companies, on the one hand, and opportunities for market entry by generic drug manufacturers, on the other hand.[6] Without question, Hatch-Waxman has increased generic drug entry. The Congressional Budget Office estimated that, by purchasing generic equivalents of brand-name drugs, consumers saved $8-10 billion on retail purchases of prescription drugs in 1994 alone.[7] The federal and state governments also are significant purchasers of pharmaceuticals, and they likewise reap substantial savings from generic drugs.

Yet, in spite of this remarkable record of success, there have been, and continue to be, competitive problems in pharmaceutical markets. Although many drug manufacturers – including both brand-name and generic companies – have settled their patent suits in a manner that does not harm competition, others have entered anticompetitive settlements without providing a corresponding benefit to consumers. Responding to some of these abuses, in 2003 Congress included provisions in the Medicare Modernization Act ("MMA") that amended the

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[4] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

[5] 21 U.S.C. § 301 *et seq.*

[6] *See infra* notes 16-33 and accompanying text. The Amendments also were intended to encourage pharmaceutical innovation through patent term extensions.

[7] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at* <http://www.cbo.gov/showdoc.cfm?index=655&sequence=0> (hereinafter "CBO Study").

Hatch-Waxman Act to require notice of settlement between brand and generic firms to the FTC and Department of Justice.

For its part, the Commission has aggressively protected competition in the pharmaceutical industry, including pursuing numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers.[8] The Commission also has filed amicus briefs on competition-related issues in a variety of pharmaceutical cases.[9] On a policy level, the Commission has promoted a greater understanding of the role of competition in the industry through multiple studies including our 2002 study entitled "Generic Drug Entry Prior to Patent Expiration" ("Generic Drug Study"), which recommended some of the changes made in the MMA.[10] Since the MMA filing requirement became effective in January 2004, Commission staff have issued annual reports on the types of patent settlements being entered.[11] Commission staff

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[8] *See, e.g.*, Federal Trade Commission, Petition for a Writ of Certiorari, *FTC v. Schering-Plough Corp.*, No. 05-273 (June 26, 2006) (denying cert. petition); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005); *Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (F.T.C.) (Dec. 8, 2003) (Commission decision and final order); *Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp.*, Dkt. No. 9297 (Apr. 5, 2002) (consent order as to American Home Products); *FTC v. Perrigo and Alpharma*, Civ. Action No. 1:04CV01397 (D.D.C. Aug. 12, 2004) (stipulated judgment); *Bristol-Myers Squibb Co.*, Dkt. No. C-4076 (Apr. 13, 2003) (consent order); *Biovail Corp. and Elan Corp. PLC*, Dkt. No. C-4057 (Aug. 20, 2002) (consent order); *Biovail Corp.*, Dkt. No. C-4060 (Oct. 4, 2002) (consent order); *Abbott Labs.*, Dkt. No. C-3945 (May 26, 2002) (consent order); *Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 22, 2000); *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (Apr. 4, 2001) (consent order); *FTC v. Mylan Labs., Inc. et al.*, 62 F. Supp. 2d 25 (D.D.C. 1999).

[9] *See, e.g.*, Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *In re Tamoxifen Litigation*, (No. 03-7641) (2d Cir. Dec. 2, 2005); Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *Teva Pharm. v. Pfizer Inc.*, (03CV-10167) (Fed. Cir. Feb. 5, 2005); Brief for the Federal Trade Commission as Amicus Curiae Supporting Appellants, *Teva Pharm. v. Pfizer Inc.*, (03CV-10167) (Fed. Cir. Feb. 5, 2005).

[10] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (hereinafter "Generic Drug Study")

[11] Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at* <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>; Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2004: A Report by the Bureau*

also have conducted empirical analyses of competition in the pharmaceutical industry, including in-depth studies by the staff of the FTC's Bureau of Economics.[12] The Commission's efforts also have included filing comments with the United States Food and Drug Administration ("FDA") regarding the competitive aspects of Hatch-Waxman implementation,[13] as well as submitting testimony before Congress.[14] Furthermore, individual Commissioners have addressed the subject

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of Competition (Jan. 2005), *available at* <http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf>.

[12] Federal Trade Commission, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies (August 2005), *available at* <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>; Federal Trade Commission, *To Promote Innovation. The Proper Balance of Competition and Patent Law and Policy* (Oct. 2003), *available at* <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>; David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002) ("Reiffen and Ward"), *available at* <http://www.ftc.gov/be/econwork.htm>; Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999), *available at* <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>.

[13] *Response to Citizen Petition by Ivax Pharmaceuticals, Inc.* (Apr. 5, 2005), *available at* <www.ftc.gov/os/2005/04/050407ltrivaxpharm.pdf> (recommending that FDA deny Ivax's request that the FDA prohibit delisting of patents from the Orange Book); *FDA: Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed*, Comment of the Federal Trade Commission (Dec. 23, 2002) ("30-Month Stay Comment"), *available at* <http://www.ftc.gov/be/v030002.pdf> (recommending modifications to FDA proposed rule on patent listing requirements and providing suggestions to the proposed patent declaration); *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Mar. 2, 2000), *available at* <http://www.ftc.gov/be/v000005.pdf> (recommending modifications to the FDA's Proposed Rule on citizen petitions intended to discourage anticompetitive abuses of the FDA's regulatory processes); *FDA: 180-DayGeneric Drug Exclusivity for Abbreviated New Drug Applications*, Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Nov. 4, 1999) ("Marketing Exclusivity Comment"), *available at* <http://www.ftc.gov/be/v990016.htm> (recommending that the FDA's Proposed Rule on 180-day marketing exclusivity be modified to limit exclusivity to the first ANDA filer and to require filing of patent litigation settlement agreements).

[14] Testimony of the Federal Trade Commission before the Committee on Judiciary, United States Senate, *Competition in the Pharmaceutical Industry* (June 17, 2003), *available at* <http://www.ftc.gov/os/testimony/108hearings.htm>; Testimony of the Federal Trade Commission before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives, *Study of Generic Drug Entry Prior to Patent Expiration* (Oct. 9, 2002), *available at* <http://www.ftc.gov/os/2002/10/generictestimony021009.pdf>; Testimony of the Federal Trade Commission before the Committee on Commerce, Science, and Transportation, United States Senate, *Competition in the Pharmaceutical Industry* (Apr. 23, 2002), *available at* <http://www.ftc.gov/os/2002/04/pharmtestimony.htm>; Testimony of the Federal Trade Commission before the Committee on the Judiciary, United States Senate, *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements* (May 24, 2001), *available at* <http://www.ftc.gov/os/2001/05/pharmtstmy.htm>.

of pharmaceutical competition before a variety of audiences, both to solicit input from affected parties and to promote discussion about practical solutions.[15]

This testimony will address the Commission's vigorous enforcement of the antitrust laws with respect to brand-name and generic drug competition, as well as current policy issues that implicate that competition and affect senior citizens' drug purchasing costs. The first two sections address how settlements of patent litigation, either alone or in combination with the 180-day exclusivity period, can delay generic entry. The testimony discusses (I) the types of patent settlements the Commission believes are anticompetitive, including possible legislative solutions to this problem, and (II) how brand companies have used 180-day exclusivity to block generic entry.

Next, the testimony reviews the antitrust implications of agreements entered outside the context of patent litigation. The testimony discusses (III) the Commission's ongoing litigation against Warner-Chilcott and Barr Laboratories, and (IV) the Commission's enforcement actions against agreements between generic companies that delay generic competition.

Finally (V), the testimony discusses the Commission's plan to study the impact of authorized generics on pharmaceutical markets.

I. Settlement of Patent Disputes in the Pharmaceutical Industry

Settlements of patent litigation are a significant threat to competition in the pharmaceutical industry when they include so-called "exclusion payments." These settlements,

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[15] *See, e g*, Deborah Platt Majoras, *A Government Perspective on IP and Antitrust Law* (June 21, 2006), *available at* <http://www.ftc.gov/speeches/majoras.htm>; Jon Leibowitz, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck! (The Role of the Commission, Congress, and the Courts)* (Apr. 24, 2006), *available at* <http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf>; Timothy J. Muris, *Competition and Intellectual Property Policy: The Way Ahead*, at 5-6 (Nov. 15, 2001), *available at* <http://www.ftc.gov/speeches/muris/intellectual.htm>.

which appear to be unique to the pharmaceutical industry, occur when a branded company shares a portion of its future profits with a potential generic entrant in exchange for the generic's agreement not to market its product. Although both the brand company and the generic company are better off financially, these settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs may be deferred for years.

A. The Benefits of Generic Competition

Generic competition in the pharmaceutical industry provides a significant benefit to consumers and, in particular, the elderly. Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at 70 to 80 percent of the brand-name counterpart, and gains substantial share from the brand-name product in a short period of time.[16] Subsequent generic entrants may enter at even lower prices and cause the earlier entrants to reduce their prices. As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80 percent of branded sales within the first full year after launch of a lower-priced generic product.[17]

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[16] *See* CBO Study, n. 6; *see generally* Reiffen & Ward, *Generic Drug Industry Dynamics*, 87 REVIEW OF ECON. & STAT. 37-79 (2005).

[17] CBO Study, xiii.

1. Statutory Background

Congress intended that the Hatch-Waxman Act would "make available more low cost generic drugs," while fully protecting legitimate patent claims.[18] The Act allows for accelerated FDA approval of a drug through an Abbreviated New Drug Application ("ANDA"), upon showing, among other things, that the new drug is "bioequivalent" to an approved drug.[19] It also encourages the development of generic drugs by declaring various research and development activities noninfringing.[20]

Pursuant to the FDC Act, a brand-name drug manufacturer seeking to market a new drug product must first obtain FDA approval by filing a New Drug Application ("NDA") that, among other things, demonstrates the drug product's safety and efficacy. At the time the NDA is filed, the NDA filer also must provide the FDA with certain categories of information regarding patents that cover the drug that is the subject of its NDA.[21] Upon receipt of the patent information, the FDA is required to list it in an agency publication entitled "Approved Drug Products with Therapeutic Equivalence," commonly known as the "Orange Book."[22]

Rather than requiring a generic manufacturer to repeat the costly and time-consuming NDA process, the Hatch-Waxman Amendments permit the company to file an Abbreviated New Drug Application ("ANDA"), which incorporates data that the "pioneer" manufacturer has

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[18] H.R. Rep. No. 857, 98th Cong., 2nd Sess., Pt. 1, at 14 (1984).

[19] 21 U.S.C. 355(j).

[20] 35 U.S.C. 271(e)(1); *see Merck KGaA* v. *Integra Lifesciences I, Ltd.*, No. 03-1237, 125 S. Ct. 2372 (June 13, 2005).

[21] 21 U.S.C. § 355(b)(1).

[22] *Id.* § 355(j)(7)(A).

already submitted to the FDA regarding the branded drug's safety and efficacy. The ANDA filer must demonstrate that the generic drug is "bioequivalent" to the relevant branded product.[23] The ANDA must contain, among other things, a certification regarding each patent listed in the Orange Book in conjunction with the relevant NDA.[24] One way to satisfy this requirement is to provide a "Paragraph IV" certification, asserting that the patent in question is invalid or not infringed.[25]

Filing a Paragraph IV certification potentially has significant regulatory implications, as it is a prerequisite to operation of the two most competitively sensitive provisions of the statute. The first of these is the automatic 30-month stay. An ANDA filer that makes a Paragraph IV certification must provide notice, including a detailed statement of the factual and legal bases for the ANDA filer's assertion that the patent is invalid or not infringed, to both the patent holder and the NDA filer.[26] Once the ANDA filer has provided such notice, a patent holder wishing to take advantage of the statutory stay provision must bring an infringement suit within 45 days.[27] If the patent holder does not bring suit within 45 days, the FDA may approve the ANDA immediately.[28] If the patent holder does bring suit, however, the filing of that suit triggers an

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[23] *Id* § 355(j)(2)(A)(iv).

[24] *Id*. § 355(j)(2)(A)(vii).

[25] *Id* ' 355(j)(2)(A)(vii)(IV).

[26] *Id* § 355(j)(2)(B). Although the patent holder and the NDA filer will often be the same person, this is not always the case. The Hatch-Waxman Amendments require that all patents that claim the drug described in an NDA must be listed in the Orange Book Occasionally, this requirement will cause an NDA filer to list a patent that it does not own.

[27] *Id*. § 355(j)(5)(B)(iii).

[28] *Id*.

automatic 30-month stay of FDA approval of the ANDA.[29] And, without FDA approval, a generic manufacturer cannot bring its product to market. The imposition of a stay can, consequently, forestall generic competition for a substantial period of time.

The second competitively sensitive consequence is the 180-day period of marketing exclusivity. To encourage generic drug manufacturers to challenge questionable patents by filing Paragraph IV certifications – a move that can potentially subject the company to costly and burdensome patent infringement litigation – the Hatch-Waxman Amendments provide that the first generic manufacturer (first-filer) to file an ANDA containing a Paragraph IV certification is awarded 180 days of marketing exclusivity, during which the FDA may not approve a potential competitor's ANDA.[30] The 180-day period is calculated from the date of the first commercial marketing of the generic drug product.[31] The potential impact of the 180-day exclusivity period is further magnified by the fact that, under the prevailing interpretation of the Hatch-Waxman Amendments, a second ANDA filer may not enter the market until the first filer's 180-day period of marketing exclusivity has expired, even if the first filer substantially delays commencement of the exclusivity period.[32] A first-filer can forfeit its exclusivity under certain conditions.[33]

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[29] *Id.*

[30] *Id.* § 355(j)(5)(B)(iv).

[31] *Id.*

[32] *See id.* § 355(j)(5)(B)(iv). As discussed in Section II, *infra*, the first ANDA filer's failure to commence its 180-day period of marketing exclusivity can create a bottleneck that prevents subsequent ANDAs from being approved and, consequently, prevents additional generic products from entering the market.

[33] *Id.* § 355(j)(5)(D); *see also infra* notes 62-64, and accompanying text.

2. Impact of Generic Competition

Experience has borne out the efficacy of the Hatch-Waxman process and the correctness of its premises – *i.e.*, that many patents will not stand in the way of generic entry if challenged, and that successful challenges can yield enormous benefits to consumers. The Commission studied all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic challengers, and found that the generics prevailed in cases involving 73 percent of the challenged drug products.[34] Many of these successes involved blockbuster drugs and allowed generic competition years before patent expiration (see chart).[35] Generic competition following successful patent challenges to Prozac, Zantac, Taxol, and Plantinol alone is estimated to have saved consumers more than $9 billion,[36] in addition to the savings to federal and state governments.

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[34] *Generic Drug Study*, at 19-20.

[35] SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp.2d 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005) (patent claiming Paxil held invalid); *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp.2d 423 (S.D.N.Y. 2002), *aff'd sub nom., In re Omeprazole Patent Litig.*, 84 Fed. App. 76 (Fed. Cir. 2003) (noninfringement of patents claiming Prilosec); *American Biosciences, Inc. v. Baker Norton Pharms. Inc.*, 2002 U.S. Dist. LEXIS 512 (C.D. Cal. Jan. 10, 2002) (patent claiming anticancer held invalid); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2001) (patent claiming antidepressant Prozac held invalid); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) (noninfringement of patents claiming Zantac).

[36] Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm., 107th Cong. (Apr. 23, 2002) (statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Ass'n) at 12, *available at* <http://commerce.senate.gov/hearings/042302jaegar.pdf>.

Examples of Generic Entry Prior to Patent Expiration from Successful Patent Challenges

Drug	First Generic Entrant	Generic Entry Date	Brand Sales Prior to Generic Entry	Expiration Date of Last Patent
Zantac	Granutec	1997	$1.6 billion	2002
Taxol	Baker Norton	2000	$1.6 billion	2013
Prozac	Barr	2001	$2.5 billion	2004
Prilosec	Kudco	2002	$3.7 billion	2018
Paxil	Apotex	2003	$2.2 billion	2017

B. Exclusion Payments Harm Consumers

By increasing the likelihood of generic entry, however, the statute also increases the incentive for brand and generic manufacturers to conspire to share, rather than compete for, the expected profits generated by sales of both brand and generic drugs. In nearly any case in which generic entry is contemplated, the profit that the generic anticipates will be much less than the profit the brand-drug company makes from the same sales. Consequently, it typically will be more profitable for both parties if the brand-name manufacturer pays the generic manufacturer to settle the patent dispute and agree to defer entry. Although both the brand-name company and

the generic company are better off with the settlement, consumers lose the possibility of an earlier generic entry, either because the generic company would have prevailed in the lawsuit or the parties would have negotiated a settlement with an earlier entry date but no payment. Instead, consumers are left with the guarantee of delayed generic entry and paying higher prices.

Congress expressly recognized the risk that the Act might promote such market allocation agreements, and implicitly directed the enforcement agencies to prosecute such agreements by amending the Hatch-Waxman Act in 2003 to require brand-name companies and generic applicants to file patent settlement agreements with the Commission and the Department of Justice. As the Senate Report explained, those amendments sought in part to stamp out the "abuse" of Hatch-Waxman law resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market."[37] In the words of Rep. Waxman, "[t]he law has been turned on its head. . . . We were trying to encourage more generics and through different business arrangements, the reverse has happened."[38]

The Commission has challenged patent settlements when it believes that brand-name and generic companies have eliminated the potential competition between them and shared the

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[37] S. Rep. No. 167, 107th Cong., 2nd Sess., at 4 (2002).

[38] Cheryl Gay Stolberg et al., *Keeping Down the Competition: How Companies Stall Generics and Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at A11 (quoting Rep. Waxman). *See also* Statement of Sen. Orrin Hatch, Senate Floor Debates on S. 812 (2002), *available at* http://hatch.senate.gov/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id ("As a coauthor of the Drug Price Competition and Patent Term Restoration Act, I can tell you that I find these type of reverse payment collusive arrangements appalling. I must concede, as a drafter of the law, that we came up short in our draftsmanship. We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition. . . . However the K-Dur case ultimately is decided, I commend [the FTC for] zealously reviewing these type of reverse payments cases to determine whether such agreements run afoul of the antitrust laws.").

resulting profits.[39] Although some have argued that all settlements include some form of consideration between the parties,[40] it is the type of consideration that matters. Other types of consideration, an early entry date or a royalty to the patent-holder or compromising on a damage claim, do not generally involve sharing the benefits that come from eliminating potential competition. Indeed, Section 1 of the Sherman Act's primary purpose is to prevent such sharing.

Initially, the Commission's enforcement efforts in this area appeared significantly to deter anticompetitive behavior. In the seven years between 1992 and 1999, there were fourteen final settlements between brand-name manufacturers and the generic first-filer.[41] Eight of those settlements between brand-name and generic first-filers included a payment from the brand-name to the generic company in exchange for the generic company's agreement not to market its product. In 1999, it was reported that the Federal Trade Commission was investigating agreements involving such payments. The Commission is not aware of any pharmaceutical settlement between a brand-name manufacturer and a generic filer that included both a payment

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[39] *Abbott Labs.*, Dkt. No. C-3945 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3945complaint.htm>; *Geneva Pharms., Inc.*, Dkt. No. C-3946 (May 22, 2000) (consent order), complaint *available at* <http://www.ftc.gov/os/2000/05/c3946complaint.htm>. The consent order in *Abbott Laboratories* is *available at* <http://www.ftc.gov/os/2000/03/abbot.do.htm>. The consent order in *Geneva Pharmaceuticals* is *available at* <http://www.ftc.gov/os/2000/03/genevad&o.htm>. The consent order in *Hoechst/Andrx* is *available at* <http://www.ftc.gov/os/2001/05/hoechstdo.htm>. *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order), complaint *available at* http://www.ftc.gov/os/2000/03/hoechstandrxcomplaint.htm. *Bristol-Myers Squibb Co.*, Dkt. No. C-4076, *available at* <http://www.ftc.gov/os/caselist/c4076.htm>.

[40] *Schering*, 402 F.3d at 1074.

[41] Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at* <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

to the generic company and an agreement by the generic company not to market its product between 2000 and the end of fiscal year 2004.[42]

During the same period, however, patent settlements did not disappear. To the contrary, in less than five years, there were at least as many settlements as there were in the seven years in which pharmaceutical companies were settling litigation with payments and restrictions on generic entry.[43] The parties simply found different ways to resolve their disputes. In other words, we were effectively enforcing the antitrust laws, and our enforcement efforts were an effective deterrent that benefitted consumers with lower priced drugs.

C. The Threat Exclusion Payment Settlements Currently Pose to Consumers

Two recent court decisions, however, have taken a lenient view of exclusion payment settlements, essentially holding that such settlements are legal unless the patent was obtained by fraud or that the infringement suit itself was a sham.[44] In the *Schering* case,[45] the Eleventh Circuit vacated a decision by the Commission finding two patent settlements to be anticompetitive. Schering-Plough Corporation ("Schering"), the manufacturer of a brand-name drug called "K-Dur 20," settled patent litigation with two manufacturers of generic counterparts, Upsher-Smith Laboratories, Inc. ("Upsher") and American Home Products Corporation ("AHP").

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[42] *Id*

[43] We lack data for the approximately three year period between the end of the Generic Drug Study and the beginning of the MMA reporting period. It is quite likely that there are additional settlements that occurred during this period for which we do not have information.

[44] *Schering-Plough Corp. v F.T.C.*, 403 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005).

[45] Federal Trade Commission, Petition for a Writ of Certiorari, *FTC v Schering-Plough Corp.*, No. 05-273 (June 26, 2006) (denying cert. petition); *Schering-Plough Corp. v. F.T.C.*, 402 F.3d 1056 (11th Cir. 2005); *Schering-Plough Corp.*, No. 9297, 2003 WL 22989651 (F.T.C.) (Dec. 8, 2003) (Commission decision and final order); *Schering-Plough Corp., Upsher-Smith Labs., and American Home Products Corp.*, Dkt. No. 9297 (Apr. 2, 2002) (consent order as American Home Products).

The two generic manufacturers agreed to forbear marketing their generic drugs until specified dates in exchange for guaranteed cash payments totaling $60 million to Upsher and $15 million to AHP. A full trial was held before an administrative law judge, and the Commission reviewed the entire record *de novo*. The Commission concluded that in each settlement, Schering had paid its generic competitors to accept the settlement and that the settlements provided Schering with more protection from competition than a settlement without a payment or simply proceeding with litigation. As a result of these agreements, Schering continued to enjoy supracompetitive profits from K-Dur 20 for several more years, at the expense of consumers.

The court of appeals set aside the Commission's decision.[46] The court began with the startling premise that "neither the rule of reason nor the *per se* analysis is appropriate" in an antitrust case involving patents.[47] The court purported to assess whether the agreement exceeded the exclusionary potential of Schering's patent, but in doing so, the court relied on the incorrect supposition that the patent provided Schering with "the legal right to exclude Upsher and ESI from the market until they proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent,"[48] and noted that there was no allegation that the patent claim was a "sham."[49] In particular, the court ruled that a payment by the patentee, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger

[46] *Schering*, 403 F.3d at 1058.

[47] *Id.* at 1065-66 (citing *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003)).

[48] *Id.* at 1066-67.

[49] *Id.* at 1068.

must have agreed to a later date in return for such payment, even if there was no other plausible explanation for the payment.[50]

The Commission sought Supreme Court review. Thirty-five states, AARP, and a patent policy think tank supported the Commission's petition. Last month, however, the Supreme Court denied certiorari review.

The Eleventh Circuit's decision already is having a negative legal and practical effect. Other courts have understood the ruling below to demand only an inquiry into the nominal reach of the patent, and not an assessment of the likelihood that the patent-holder could successfully effect exclusion through patent litigation.[51] Indeed, the Second Circuit, in ruling in similar cases, followed the Eleventh Circuit's holding and expressly embraced the "sham" standard.[52] Although there was a five-year hiatus in pay-offs to generics after the Commission commenced enforcement actions aimed at exclusion payment settlements, pharmaceutical companies have once again started entering into settlement agreements that include both compensation in various forms to generic challengers and restrictions on generic market entry.[53] There were three such agreements in fiscal 2005, two of which occurred after the Eleventh Circuit's decision in *Schering*. In the current fiscal year, we have seen significantly more settlements with payments and a restriction on entry– seven of ten agreements between brand-name and generic companies

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[50] *Id.* at 1076.

[51] *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 539 (E.D.N.Y. 2005), *appeal docketed*, No. 05-2851 (2d Cir. June 7, 2005) ("Cipro") (the ruling below "is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a post hoc analysis of the patent's validity").

[52] *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005)

[53] Bureau of Competition Report, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005: A Report by the Bureau of Competition* (Apr. 2006), *available at* <http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf>.

included a payment from the brand-name to the generic company and an agreement to defer generic entry.[54]

The economic implications of the courts of appeals' rulings, which seem to invite collusive arrangements between brand-name drug companies and generic challengers, are staggering. American consumers and health plans spend over a hundred billion dollars on prescription drugs each year.[55] Of the twenty top-selling prescription drugs in the United States in 2004, eleven (with annual sales of nearly $25 billion) were the subject of litigation by generic firms seeking to enter the market under the terms of the Hatch-Waxman Act.[56] The prospect of consumer benefit from such challenges is enormous, to the extent that they lead to early, non-infringing generic entry. Under the courts of appeals' rulings, however, the parties in such cases will have the strong economic incentive discussed above to enter into settlements that share the benefits of continued monopoly prices and deprive consumers of the benefit of low-cost, non-infringing generic drugs.

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[54] *See* Leibowitz, *supra* note 15.

[55] In 2002 alone, for example, Americans spent over $160 billion for prescription drugs. *See* The Henry J. Kaiser Family Foundation, *Prescription Drug Trends*, at 1 (Oct. 2004). Retail prescription prices have increased an average of 7.4% annually from 1993-2003, almost triple the average inflation rate of 2.5% during that same period. *Id.*; *see also* Centers for Medicare & Medicaid Services, *Highlights – National Health Expenditures*, 2003, at 1 (Jan. 1, 2005) (prescription drug spending rose 14.9% in 2002 and 10.7% in 2003). They are projected to increase at an even higher average rate over the next decade (10.7% annually between 2004 and 2013). *Prescription Drug Trends* at 2. For the past two decades, spending for prescription drugs has been the fastest growing component of the national healthcare spending. *Id.* at 1.

[56] *See* Drug Topics, *Top 200 Brand-Name Drugs by Retail Dollars in 2004* (Feb. 21, 2005), <http://www.drugtopics.com> (listing top-selling drugs). SEC filings and public statements by the manufacturers of the twenty top-selling drugs indicate that the following eleven drugs are subject to litigation by generic rivals: Lipitor, Effexor-XR, Plavix, Celebrex, Neurontin, Protonix, Norvasc, Zyprexa, OxyContin, Fosamax, and Risperdal. See, e.g., Pfizer Inc., Form 10-Q (Aug. 8, 2005); Wyeth, Form 10-Q (Aug. 5, 2005); Purdue Pharma, L.P., Press Release (June 8, 2005).

One need look no further than the investment community for confirmation of the danger these rulings present. One analyst report describes the Eleventh Circuit's *Schering* decision as having "opened a Pandora's box of settlements" and observes that the decision provided "significant value" to both brand-name and generic companies.[57] Left out of the equation is the impact of the decision on consumers.

The issue of exclusion payments has been the subject of significant debate, but the Commission's position is clear. Where a patent holder makes a payment to a challenger to induce it to agree to a later entry than it would otherwise agree to, consumers are harmed *either* because a settlement with an earlier entry date might have been reached, *or* because continuation of the litigation without settlement would yield a greater prospect of competition.[58] Some who disagree with the Commission's position argue that we must presume the validity of the patent, and even infringement, and its exclusionary power for the full term unless patent litigation proves otherwise. They also argue that we must permit parties to settle patent litigation, which they may choose to do regardless of their positions on the merits, according to their own risk calculus at the time. These arguments, however, ignore both the law and the facts. There is no question that the result of patent litigation, and therefore the timing of generic entry, is uncertain. But the antitrust laws prohibit the paying of a potential competitor, as well as an existing competitor, to

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[57] Stephanie Kirchgaessner and Patti Waldmeir, *Drug Patent Payoffs Bring a Scrutiny of Side-Effects*, Financial Times UK, Apr. 25, 2006, 2006 WLNR 6910048 (quoting S G. Cowen & Co. analyst's report).

[58] For example, to return to the hypothetical patent claim with a 50% chance of success, if there are 10 years remaining in the patent term, continued litigation between the parties affords consumers an overall expected value of 5 years' competition, taking into account the likelihood of the two possible outcomes. If the parties instead reach a settlement in which the patent holder makes a payment to the challenger, and the challenger agrees to enter only one year prior to the expiration date, consumers are worse off, on average, than had the litigation gone forward. The court of appeals' approach, by contrast, would automatically endorse such a settlement because it is within the outer, nominal bounds of the patentee's claims.

stay out of the market, even if the entry is uncertain. We disagree with the argument that generic entry before the end of a patent term is too uncertain or unlikely to be of competitive concern, because Congress spoke on the issue and we know that would-be generic entrants have enjoyed a nearly 75 percent success rate in patent litigation initiated under Hatch-Waxman. As for the argument that challenging such payoffs will deter settlements, which generally are favored, legitimate patent settlements – using means other than exclusion payments – continued to occur without hindrance from the Commission decision.

Under the rulings in the Second Circuit's *Tamoxifen* decision and the Eleventh Circuit's *Schering* decision, exclusion payment settlements are legal unless the patent was obtained by fraud or the suit is a sham. Given that the brand-name and generic company are both better off avoiding the possibility of competition and sharing the resulting profits, there can be little doubt that, should those rulings become the controlling law, we will see more of these settlements and less generic competition. Already, we are seeing their return. The cost to consumers, insurers, employers, and the government will be tremendous. Although the Commission will continue to be vigilant in this area, litigating another case to conclusion will take years and provide little relief for those consumers harmed in the interim.

Prozac provides a telling example. In the course of the patent litigation, the generic company offered to drop its challenge if the brand-name company would pay it $200 million. The brand-name company refused because, in part, it believed such a settlement would violate the antitrust laws. The generic won the patent litigation, and consumers – and federal and state governments – saved over two billion dollars.[59] Under the legal standard articulated in the

[59] Stephanie Kirchgaessner & Patti Waldmeir, *Drug patent payoffs bring a scrutiny of side-effects*, FIN. TIMES UK, Apr. 25, 2006, 2006 WLNR 6910048.

Schering and *Tamoxifen* cases,[60] the settlement would have been legal, generic entry would not have occurred, and consumers would have had to pay higher prices until patent expiration.

D. Legislative Solutions to Anticompetitive Settlements

The Commission supports legislation addressing this problem. We recognize that crafting legislation that accomplishes those goals may be challenging, however. A law must be broad enough to prevent evasion or other anticompetitive practices that could render the legislation ineffective, but it should avoid unwarranted deterrence to settlement of suits. For these reasons, we strongly support the intent behind S. 3582, the "Preserve Access to Affordable Generics Act" – bipartisan legislation introduced by Senators Kohl, Leahy, Grassley, and Schumer. We would welcome the opportunity to work with Congress on any such legislative initiatives.

II. The 180-Day Exclusivity as a Bottleneck to Prevent Generic Entry

The impact of the courts of appeals' decisions sanctioning settlements incorporating exclusionary payments will be magnified by the effect of the Hatch-Waxman Act's 180-day exclusivity. Because of recent court decisions, settlements between a brand-name company and a first generic filer for a delayed entry date are more likely to create a bottleneck that prevent *any* generic competition through operation of the first generic filer's 180-day exclusivity.

When a first generic applicant enters into an agreement with a brand-name manufacturer to delay entering the market, either with or without an accompanying payment, the generic typically will not trigger the running of its 180-day exclusivity period until it enters the market on the agreed-upon date. For that reason, the first generic applicant's 180-day exclusivity period

[60] *See supra* notes 44-50 and accompanying text.

will create a bottleneck that prevents any subsequent generic applicant from entering the market until the period runs.[61] Such a bottleneck would obviously benefit only the brand manufacturer and the first generic applicant, to the detriment of subsequent generic applicants and consumers. A subsequent generic can relieve the bottleneck only by triggering a forfeiture event that forces the first generic filer to either use or lose its exclusivity period within 75 days. One such forfeiture event[62] is a court decision[63] that the patent supporting the 180-day exclusivity period is invalid or not infringed.[64]

A problem arises if the brand-name company does not sue the subsequent ANDA filer, thereby eliminating the possibility that the generic company will obtain a favorable court decision and relieve the bottleneck. Having settled with the first challenger, perhaps for delayed entry, a brand-name company can preempt all subsequent generic challenges and the chance of any earlier generic entry by declining to sue subsequent ANDA filers. Indeed, a troubling trend by brand-name companies towards employing just such a strategy is increasingly evident.[65]

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[61] *See Generic Drug Study* at vii-xi, 57-58, 62-63.

[62] The other forfeiture events established by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 P.L. No. 108-173 (hereinafter "MMA") are a court-entered settlement that the patents are invalid or not infringed, or withdrawal of the patents from the Orange Book by the brand company. MMA § 1102(a)(1), amending 21 U.S.C. § 355(j)(5)(B)(iv).

[63] The decision must be "a final decision from which no appeal (other than a petition to the Supreme Court for a writ of *certiorari)* has been or can be taken that the patent is invalid or not infringed." MMA, § 1102(a)(1), amending 21 U.S.C. § 355(j)(5)(B)(iv).

[64] MMA § 1102(a)(1), amending 21 U.S.C. § 355(j)(5)(B)(iv). Prior to the MMA's amendment of the Hatch-Waxman Act, a court decision holding a challenged patent to be invalid or not infringed would trigger the running of the 180-day exclusivity period, rather than triggering a forfeiture event. In the MMA, however, Congress did not change the *type* of court decision (*e.g.*, one holding that the patent is invalid or not infringed) that would forfeit the exclusivity.

[65] *See, e.g., Teva Pharms. USA, Inc., v. FDA*, 2005 WL 2692489 (D.D.C. Oct. 21, 2005); *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp.2d 187 (S.D.N.Y. 2005), *aff'd*, 159 Fed.Appx. 1013, 2005 U.S. App. LEXIS 28102 (Fed Cir. 2005); *Glaxo Group Ltd. v. Dr. Reddy's Labs, Ltd.*, 325 F. Supp.2d 502 (D.N.J. 2004); *Mutual Pharm. Co. v. Pfizer, Inc.*, 307 F. Supp.2d 88 (D.D.C. 2004).

Some generic companies facing this scenario have attempted to bring declaratory judgment actions of non-infringement and invalidity,[66] but that strategy has been unsuccessful thus far. A recent decision of the Federal Circuit, *Teva v. Pfizer*,[67] held that declaratory judgment is unavailable in this situation for lack of a Constitutionally-required case or controversy unless the brand-name company has raised a reasonable apprehension of suit in the subsequent ANDA filer. In that case, Pfizer, the brand-name manufacturer, had settled patent litigation with Ivax, the first generic applicant, with Ivax agreeing to delay entering the market for approximately two years. As a result, Ivax's 180-day exclusivity blocked Teva, the subsequent generic applicant, from entering. After Pfizer refused to bring suit against Teva or to provide it with a covenant not to sue, Teva filed an action seeking a declaration of non-infringement and invalidity. The district court dismissed the case without prejudice for lack of controversy and the Federal Circuit affirmed.[68]

Quite recently, the situation worsened. In March of this year, the D.C. Circuit revisited the issue and held that its prior decision did not bind FDA to treat dismissal of a declaratory judgment action as a court decision sufficient to trigger the exclusivity period.[69] Following that

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[66] The MMA amendments to the Hatch-Waxman Act state that the district courts, "shall, to the extent consistent with the Constitution, have subject matter jurisdiction" over such declaratory judgment actions. MMA § 1101(d). Those same amendments specify that a court decision of invalidity or non-infringement in a declaratory judgment action triggers a forfeiture event. MMA § 1102(a)(2).

[67] *Teva Pharms USA, Inc v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir.), *cert. denied*, 126 S. Ct. 473 (2005).

[68] On appeal to the Federal Circuit, the Commission filed an amicus in support of Teva's position that there was a case or controversy. Brief for the Federal Trade Commission as Amicus Curiae Supporting *en banc* petition, *Teva Pharm v Pfizer Inc*, (03CV-10167) (Fed. Cir. Feb. 5, 2005). The Commission argued that declaratory judgment actions by generic applicants play a vital role in the Hatch-Waxman regime by permitting them to eliminate the bottlenecks that delay them from entering the market. The Commission further argued that Teva's action satisfied the Supreme Court's test for identifying an actual controversy under Article III of the Constitution.

[69] *Teva Pharms USA, Inc v. FDA*, 441 F.3d 1 (D.C. Cir. 2006).

decision, FDA reversed its previous policy and no longer treats any dismissal of a declaratory judgment action, even those made with prejudice and having preclusive effect on the issues of infringement and validity, as a court decision for purposes of triggering the exclusivity period. Last month, the D.C. Circuit upheld that decision in *Apotex v. FDA*.[70]

There is a potential legislative remedy, however. At the time that the Commission released its Generic Drug Study in 2002, the D.C. Circuit had held that a dismissal of a declaratory judgment action for lack of a case or controversy was a court decision of non-infringement sufficient to trigger the 180-day exclusivity and clear the bottleneck.[71] Because of its concern with the bottleneck scenario described here, the Commission recommended that Congress codify this decision and clarify that dismissal of a declaratory judgment action brought by a generic applicant could trigger the 180-day exclusivity.[72] The 2003 amendments to the Hatch-Waxman Act did not incorporate this recommendation.

As a result of the Federal Circuit's decision in *Teva v. Pfizer* and the D.C. Circuit's decision in *Apotex v. FDA*, a subsequent generic filer that faces a bottleneck but has not been sued has no mechanism to relieve that bottleneck. It cannot pursue a declaratory judgment action, and dismissal of that attempt will not trigger the 180-day exclusivity or a forfeiture event. Even if the subsequent filer has a strong case for noninfringement, the bottleneck postpones consumer access to any lower-priced generic version of the drug. Indeed, in those circumstances, it is contrary to the Hatch-Waxman Act's purposes of encouraging meritorious patent challenges

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[70] *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006)

[71] *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999)

[72] *Generic Drug Study* at x-xi.

and promoting generic entry to delay market entry by later applicants when the brand-name manufacturer and first generic applicant are involved in protracted litigation, or have settled their litigation without resolving the issues of validity or infringement.

For these reasons, the Commission reiterates the recommendation of the Generic Drug Study: Congress should clarify that dismissal of an action brought by a generic applicant seeking a declaratory judgment constitutes a forfeiture event for the 180-day exclusivity period.

III. Warner-Chilcott Barr: Challenging a Naked Agreement not to Compete

Agreements between brand-name and generic companies entered outside of patent litigation can also harm consumers. Last year the Commission filed an action against Warner Chilcott and Barr Laboratories, two sellers of prescription drugs.[73] The Commission alleges that two companies entered an agreement not to compete that was not part of a patent settlement.[74] Warner Chilcott sells Ovcon 35 ("Ovcon"), an oral contraceptive used to prevent pregnancy. Barr is the only company approved by the FDA to sell a generic version of the drug in competition with Warner Chilcott's brand Ovcon. Prior to the challenged agreement, Barr planned to compete with Warner Chilcott by selling Barr's lower-priced generic Ovcon once Barr received FDA approval. Both Warner Chilcott and Barr predicted that entry of Barr's lower-priced generic into the market would reduce Warner Chilcott's higher-priced brand Ovcon's sales, by capturing approximately 50 percent of Ovcon's business in the first year alone.

The complaint alleges that to forestall this competitive threat and to protect its Ovcon sales, Warner Chilcott entered into an agreement with Barr preventing entry of Barr's generic

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[73] *F.T.C. v Warner Chilcott et al*, Civ. Action No. 1:05-CV-2179 (D.D.C. Nov. 7, 2005).

[74] The Complaint is *available at* <http://www.ftc.gov/os/caselist/0410034/051107comp0410034%20.pdf>

Ovcon into the United States for five years. In exchange for Barr's agreement to keep its generic Ovcon off the market, Warner Chilcott paid Barr $20 million. Instead of entering and competing, Barr would agree to be available as a second supplier of Ovcon to Warner Chilcott if Warner Chilcott so requested. The complaint charges that the effect of this anticompetitive agreement between Warner Chilcott and Barr has been to deprive purchasers of the choice of a lower-cost generic alternative to Warner Chilcott's higher-priced brand Ovcon.

The case is pending in the U.S. District Court for the District of Columbia. The Commission is seeking appropriate injunctive relief. Thirty-four states and the District of Columbia also filed a case against Warner Chilcott and Barr Laboratories in the same court. In addition, plaintiffs representing both direct purchasers and indirect purchasers have filed suit, seeking treble damages. Discovery in the government enforcement actions closes at the end of this year. The court has not set a trial date.

IV. Agreements between Generic Manufacturers

Although agreements between generic entrants have attracted significantly less attention than those between brand-name and generic companies, they too can raise competitive concerns and may draw antitrust scrutiny, and the Commission challenges agreements between generic entrants when they are anticompetitive. As in the case of agreements between brand-name companies and generic applicants, the economic incentives to collude can be strong. Studies indicate that the first generic typically enters the market at 70 to 80 percent of the price of the corresponding brand[75] and rapidly secures as much as a two-thirds market share. The second generic typically enters at an even lower price and, like the first, rapidly secures market share.

[75] *Supra* page 6.

Collusion between the generic firms can thus be a means of preventing price erosion in the short term, though it may become substantially less feasible if subsequent ANDAs are approved and additional competitors enter the market.

In August 2004, the Commission entered a stipulated judgment with two generic drug manufacturers to resolve charges that they entered into a horizontal market allocation.[76] According to the Commission's complaint, Perrigo and Alpharma were the only two approved manufacturers of a generic over-the-counter product that is bioequivalent to Children's Motrin (store-brand Children's Motrin), a drug product to relieve pain and inflammation in children.[77] The Commission's complaint alleges that, prior to entering the challenged agreement, Perrigo and Alpharma aggressively competed to secure customers for their respective product launches in June 1998.

In April 1998, because of a change in the interpretation of the FDA's regulations, Alpharma became entitled to the 180-day exclusivity. Alpharma's exclusivity rights blocked the FDA from granting final approval to Perrigo's ANDA. The complaint alleges that Perrigo approached Alpharma about entering an agreement that would allow Perrigo to compete during the 180-day exclusivity period.

On June 16, 1998, Alpharma and Perrigo signed an agreement that eliminated the companies' vigorous competition to secure customers of store-brand children's liquid ibuprofen. Under the agreement, Alpharma relinquished its exclusivity but promised not to compete with its

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[76] *FTC v. Perrigo and Alpharma*, Civ. Action No. 1:04CV01397 (D.D.C. Aug. 12, 2004); *see also*, *Biovail Corp.* and *Elan Corp. PLC*, Dkt. No. C-4057 (Aug. 15, 2002), consent order *available at* <http://www.ftc.gov/os/2002/08/biovaldo.pdf>.

[77] The Commission's complaint against Alpharma and Perrigo is *available at* <http://www.ftc.gov/os/caselist/0210197/040812comp0210197.pdf>.

generic Children's Motrin product for seven years. Perrigo obtained the exclusive right to do so during that period. In exchange for Alpharma's promises not to compete, Perrigo agreed to pay Alpharma a lump sum fee and royalty on Perrigo's net sales of store-brand Children's Motrin.

The Commission sought and obtained a permanent injunction in federal court. Under the stipulated orders, the defendants (1) agreed to pay over six million dollars to customers that were allegedly overcharged, (2) agreed not to enter similar agreements in the future, and (3) agreed to provide notice of other generic-generic agreements that either defendant enters.[78]

V. Authorized Generics

A new strategy in the pharmaceutical industry is the brand-name company's marketing of a so-called "authorized generic" during the 180-day exclusivity period. An authorized generic is chemically identical to a particular brand-name drug, which the brand-name manufacturer authorizes to be marketed as a generic version under the approval that the FDA granted for the brand-name drug. The brand-name manufacturer either sells the authorized generic itself through a subsidiary or licenses a generic firm to sell the authorized generic. The label typically differs for the brand-name drug and its authorized generic equivalent, but the drug product is exactly the same.

Issues have been raised regarding the impact of authorized generics and the 180-day exclusivity period. As discussed above, the first generic applicant to file an application with a

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[78] The stipulated order against Alpharma is *available at* <http://www.ftc.gov/os/caselist/0210197/040812alpharma.pdf>. The stipulated order against Perrigo is *available at* <http://www.ftc.gov/os/caselist/0210197/040812perrigo.pdf>.

The Commission also is active in merger enforcement involving the pharmaceutical industry. In a consent order finalized in March 2006, the Commission ordered Teva Pharmaceutical Industries and IVAX Corporation to divest 15 generic pharmaceutical products before allowing Teva's $7.4 billion acquisition of IVAX to proceed. *Teva Pharm Indus Ltd., and IVAX Corp.*, File No. 051 0214, Dkt. No. C-4155 (Mar. 7, 2006), *available at* http://www.ftc.gov/os/caselist/0510214/0510214do060307.pdf.

Paragraph IV certification (claiming that patent protecting the brand drug is either invalid or not infringed) receives 180 days of market exclusivity, which means the FDA cannot approve any additional ANDA filers until 180 days after the first-filer begins marketing its product. The 180-day marketing exclusivity period does not preclude competition from NDA-approved authorized generics, however.[79]

In recent years and with increasing frequency, brand-name drug manufacturers have begun to market authorized generic drugs at precisely the same time that a paragraph IV generic is beginning its period of 180-day marketing exclusivity. The likely effects of this practice on generic competition have been subject to some debate. In the short run, the entry of an authorized generic drug may benefit consumers by creating additional competition that lowers generic prices further than if only the paragraph IV generic were marketed. Many generic manufacturers assert, however, that in the long run consumers will be harmed because an expectation of competition from authorized generics will significantly decrease the incentives of generic manufacturers to pursue entry prior to patent expiration, especially for "non-blockbuster" drugs. For a generic manufacturer, the additional competition from an authorized generic may result in significantly less profit during the period of 180-day exclusivity than if the generic manufacturer had no authorized-generic competition during that time. Another concern is that, in the context of settlement, the brand-name manufacturer will promise to forego introducing an authorized generic in exchange for the first-filer agreeing to push back its entry date.

There is no publicly available, comprehensive economic study that assesses the likely short- and long-run effects of entry by authorized generics on generic competition. Thus, the

[79] *Teva Pharm. Indus. v. FDA*, 410 F.3d 51 (D.C. Cir. 2005).

Commission has proposed to undertake such a study to examine both the likely short-term competitive effects of authorized generic drug entry and, to the extent possible, the likely long-term impact of entry by authorized generic drugs on competition by generic manufacturers. The Commission stated its intention to rely on data and information from the FDA, brand manufacturers, independent generic manufacturers, and authorized generic companies. In March of this year, the Commission issued a notice in the Federal Register describing the study and the types of information it would be seeking. The Commission received public comments through the end of June and is now reviewing those comments. After the Commission finishes reviewing those comments and makes any changes to the study, it will publish a second notice and seek OMB's approval for the subpoenas.

Conclusion

Thank you for this opportunity to share the Commission's views on the barriers to generic entry. The Commission looks forward to working closely with the Committee, as it has in the past, to ensure that competition in this critical sector of the economy remains vigorous.

EXHIBIT J

No. 05-608

In the Supreme Court of the United States

MEDIMMUNE, INC., PETITIONER

v.

GENENTECH, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

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QUESTION PRESENTED

Whether Article III's grant of jurisdiction of "all Cases * * * arising under * * * the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. 2201(a), requires a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable, or not infringed.

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MEDIMMUNE, INC., PETITIONER

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INTEREST OF THE UNITED STATES

This case presents the question whether a patent licensee in good standing may challenge the validity and scope of the licensed patent in federal court. The United States Patent and Trademark Office (PTO or Patent Office) is responsible for "the granting and issuing of patents," 35 U.S.C. 2(a), as well as for advising the President on domestic and international issues of patent policy, 35 U.S.C. 2(b)(8). Several federal agencies, including in particular the National Institutes of Health, are extensively engaged in the licensing of patented inventions to private entities, and the United States is also a licensee of various patents. In addition, this case implicates core concerns of the Federal Trade Commission and the Antitrust Division of the United States Depart-

ment of Justice, because intellectual property licensing can enhance consumer welfare by allowing for the efficient exploitation of intellectual property, but the existence of invalid patents in the marketplace can impede efficient licensing, hinder competition, and undermine incentives for innovation.[1] The government accordingly has a substantial interest in this Court's resolution of the question presented.

STATEMENT

1. The federal Declaratory Judgment Act (the Act) provides that "[i]n a case of actual controversy within its jurisdiction," any court of the United States "may declare the rights and other legal relations of any interested party," without regard to whether "further relief is or could be sought." 28 U.S.C. 2201(a); see Fed. R. Civ. P. 57. Integral to the Declaratory Judgment Act is the requirement of an "actual controversy." For years prior to Congress's adoption of the Act, "there were responsible expressions of doubt that constitutional limitations on federal judicial power would permit any federal declaratory judgment procedure." *Public Serv. Comm'n* v. *Wycoff Co.*, 344 U.S. 237, 241 (1952). In 1933, how-

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[1] See generally Federal Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (*FTC Innovation Report*), *available at* <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (last visited May 11, 2006); U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995) (*DOJ/FTC Licensing Guidelines*), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132, at 20,733 (1995), *available at* <http://www.usdoj.gov/atr/public/guidelines/0558.pdf> (last visited May 11, 2006); see also U.S. Dep't of Justice, *Report of the Department of Justice's Task Force on Intellectual Property* (2004), *available at* <http://www.usdoj.gov/olp/ip_task_force_report.pdf> (last visited May 11, 2006).

ever, this Court held that a declaratory judgment action arising from the Tennessee state courts presented a justiciable case or controversy. *Nashville, Chattanooga & St. Louis Ry.* v. *Wallace*, 288 U.S. 249, 264-265 (1933). The *Wallace* Court emphasized that, notwithstanding the absence of a claim for injunctive or other coercive relief, the case presented a concrete legal dispute "of the kind which this court traditionally decides." *Id.* at 262. The "declaratory" nature of the remedy sought did not render the case nonjusticiable under Article III: "[T]he Constitution does not require that the case or controversy should be presented by traditional forms of procedure, invoking only traditional remedies. The judiciary clause of the Constitution defined and limited judicial power, not the particular method by which that power might be invoked." *Id.* at 264.

Congress enacted the Declaratory Judgment Act in the following year. See *Wycoff*, 344 U.S. at 241-242. The Senate committee report explained that the *Wallace* decision had dissipated the prevailing confusion between declaratory judgments and impermissible advisory opinions. See S. Rep. No. 1005, 73d Cong., 2d Sess. 5 (1934). Thus, "[t]he Federal bill specifically provides for declaratory adjudication only 'in cases of actual controversy.' That precludes hypothetical, academic, or moot cases. The words 'in cases of actual controversy' are designed to make certain what would be obvious even without them." *Ibid.*

This Court subsequently upheld the constitutionality of the Declaratory Judgment Act, highlighting both the breadth of the remedy thereby created and the limitations imposed by Article III on its administration: "The Declaratory Judgment Act must be deemed to fall within th[e] ambit of congressional power, so far as it

authorizes relief which is consonant with the exercise of the judicial function in the determination of controversies to which under the Constitution the judicial power extends." *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 240 (1937).

2. a. Petitioner MedImmune, Inc., is a biotechnology company whose principal product is Synagis®, a drug used in the prevention of respiratory tract disease in infants. Pet. App. 21a. In 1997, petitioner entered into a patent license agreement with respondents Genentech, Inc., a biotechnology company, and City of Hope, a nonprofit organization. *Id.* at 4a, 21a-22a, 28a-29a. That license agreement covered, among other things, a then-pending patent application, which eventually matured into U.S. Patent No. 6,331,415 (Cabilly II patent). *Id.* at 4a, 28a.[2]

In December 2001, the PTO issued the Cabilly II patent, which was assigned to respondents. Pet. App. 3a-4a, 21a-22a.[3] Shortly thereafter, respondents in-

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[2] The Cabilly II patent is a continuation of respondents' Cabilly I patent, which the license agreement also covered. Pet. App. 2a.

[3] In 1990, the PTO declared an "interference" proceeding between the then-pending Cabilly II application and U.S. Patent No. 4,816,397 (Boss patent), which was owned by CellTech R&D, Ltd. Pet. App. 2a. In 1998, petitioner separately entered into a license agreement with CellTech for rights to the Boss patent. *Id.* at 4a. By obtaining licenses from both CellTech and respondents, petitioner ensured that it would have enforceable license rights irrespective of which side prevailed in the interference proceeding. Also in 1998, the PTO decided that the Boss patent had priority and administratively cancelled respondents' Cabilly II application. *Cabilly* v. *Boss*, 55 U.S.P.Q. 2d (BNA) 1238 (BPAI 1998). After respondents challenged that determination in federal court, they entered into a settlement agreement with Celltech which provided that the Cabilly II application was entitled to priority over the Boss

formed petitioner that they believed Synagis® was covered under the patent and, consequently, that sales of Synagis® were subject to royalties under the parties' 1997 license agreement. *Id.* at 4a. Petitioner initially denied that Synagis® infringed the Cabilly II patent, but soon began paying the demanded royalties, informing respondents that its payments were made "under protest and with reservation of all of our rights." J.A. 426; see J.A. 133. Petitioner maintains that it has continued to pay royalties and otherwise remain in good standing under its license agreement only to avoid the risk of an infringement action by respondents to enjoin sales of Synagis®, which petitioner claims accounts for over 80% of its revenues. J.A. 386-389. In 2003, petitioner filed this action for a declaratory judgment that the Cabilly II patent is invalid, unenforceable, and not infringed by Synagis®. Pet. App. 4a, 22a.

b. The district court dismissed petitioner's complaint for lack of jurisdiction based on the Federal Circuit's then-recent decision in *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376, cert. dismissed, 543 U.S. 941 (2004). See Pet. App. 28a-31a. In *Gen-Probe*, the Federal Circuit applied its two-part test for determining whether there is an "actual controversy" under the Declaratory Judgment Act in patent cases, the first prong of which

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patent. In return, Celltech obtained the right to share in all royalties that respondents received on the Cabilly II application and any resulting patents. The parties' settlement was conditioned on issuance of a court order vacating PTO's cancellation of the Cabilly II application and directing PTO to issue the Cabilly II patent. J.A. 334-335. At the joint request of the parties, the district court issued an order and entered judgment to that effect. J.A. 343-348. After further proceedings before the PTO, the PTO issued the Cabilly II patent. Pet. App. 3a-4a.

requires that the declaratory judgment plaintiff must labor under "a reasonable apprehension * * * that it will face an infringement suit." 359 F.3d at 1380.[4] *Gen-Probe* held that, as a matter of law, a patent licensee in good standing cannot establish an "actual controversy" with the patent owner, because the license agreement itself "obliterate[s] any reasonable apprehension of a lawsuit." *Id.* at 1381. Although the district court in this case suggested that it harbored "serious misgivings" about the wisdom of the *Gen-Probe* rule, it discerned "no relevant facts that distinguish this case" and concluded that it had no choice but to dismiss. Pet. App. 31a.[5]

3. The court of appeals affirmed, concluding that *Gen-Probe* was dispositive of the question of justiciability. Pet. App. 1a-9a.[6] The court of appeals distinguished *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969), on the ground

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[4] The Federal Circuit's two-part test requires "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Gen-Probe*, 359 F.3d at 1380 (quoting *BP Chems. Ltd.* v. *Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)).

[5] The district court also rejected on the merits petitioner's antitrust claims, which included a claim that the interference settlement between respondents and Celltech (see note 3, *supra*) was collusive and fraudulent. See Pet. App. 22a; see also *id.* at 9a-15a.

[6] The Federal Circuit also rejected petitioner's remaining contentions on appeal, including a variety of challenges to the district court's disposition of petitioner's antitrust claims. Pet. App. 9a-17a. Those other issues are not before this Court. Judge Clevenger dissented from aspects of the court's holding on those remaining issues, but joined in full the court's dismissal of petitioner's declaratory judgment claims under the *Gen-Probe* rule. See *id.* at 17a-20a.

that "this case does not raise the question of whether patent invalidity is available as a defense to suit against a defaulting licensee—the licensee estoppel theory that was laid to rest in *Lear*—for there is no defaulting licensee and no possibility of suit." Pet. App. 6a. Rather, the court reasoned, "the issue here is not one of estoppel, but of availability of the declaratory judgment procedure." *Ibid.* In reaffirming the *Gen-Probe* rule, the court of appeals concluded that allowing petitioner to sue would "distort[] the equalizing principles that underlie the Declaratory Judgment Act." *Id.* at 7a. If petitioner's interpretation of the "actual controversy" requirement were to prevail, the Federal Circuit reasoned, the patentee, having contracted away its right to sue for infringement, would find itself "in continuing risk of attack on the patent whenever the licensee chooses—for example, if the product achieves commercial success—while the licensee can preserve its license and royalty rate if the attack fails." *Ibid.*[7]

[7] During the pendency of this case, a request was filed with the PTO for ex parte reexamination of the Cabilly II patent. See generally 35 U.S.C. 301 *et seq.* PTO reexamination is an administrative proceeding that may, but need not, result in the limitation or cancellation of some or all of the claims in a patent. See 35 U.S.C. 301-307 (2000 & Supp. III 2003) (ex parte reexaminations); see also 35 U.S.C. 311-318 (2000 & Supp. III 2003) (inter partes reexaminations). PTO granted the request and, in September 2005, provisionally rejected all of the claims of the Cabilly II patent as invalid for "obviousness-type double-patenting." *Patent of Cabilly*, Application No. 90/007,542, at 2-3 (PTO Sept. 13, 2005), *available in* Public PAIR (PTO); see *In re Berg*, 140 F.3d 1428, 1431-1432 (Fed. Cir. 1998) (explaining that "obviousness-type double patenting" is a judge-made doctrine that requires "rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent" in order "to prevent an unjustified extension of the term of the right

SUMMARY OF ARGUMENT

The Federal Circuit has adopted a restrictive test to determine the existence of an "actual controversy" in declaratory judgment cases that categorically precludes licensees in good standing from challenging patents under which they are licensed. Nothing in Article III, the Declaratory Judgment Act, or this Court's cases warrants such a special rule of justiciability for patent cases.

This Court has consistently held that whether a complaint alleges an "actual controversy" for purposes of the Declaratory Judgment Act presents a fact-sensitive issue that requires case-by-case determination. The question in each case essentially turns on whether the parties are involved in a substantial controversy that is sufficiently concrete and real that the court can resolve it through declaratory relief. When a plaintiff requests a declaration based on generalized facts and abstract legal claims, an actual controversy is lacking. But when the parties are truly adversarial, and the dispute is factually and legally concrete such that the requested declaration will definitely resolve a specific dispute, a justiciable controversy is present.

In patent cases, however, the Federal Circuit has "synthesi[zed]" this Court's contextual approach into a two-part test, which the court of appeals rigidly applies. Pet. App. 7a; *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376, 1379-1382, cert. dismissed, 543 U.S. 941 (2004). Under that test, a declaratory judgment plaintiff must

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to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later"). The reexamination of the Cabilly II patent remains pending before the PTO.

have a "reasonable apprehension" of a suit for infringement by the patentee before a justiciable "case or controversy" will be recognized. In the court of appeals' view, therefore, a licensee in good standing cannot, as an Article III matter, challenge a patent under which it is licensed because the licensee can have no reasonable apprehension of an infringement suit.

That limitation on the availability of declaratory relief cannot be squared with this Court's cases or with the congressional purposes underlying the Act. As demonstrated by decisions of this Court involving pre-enforcement challenges to statutes, it is sufficient for a declaratory judgment plaintiff to demonstrate a genuine risk of enforcement and a reasonable likelihood that he would engage in the proscribed conduct if the threat were removed. A declaratory judgment plaintiff need not run the risks entailed in actually violating the law in order to make out an "actual controversy." See, *e.g.*, *Steffel* v. *Thompson*, 415 U.S. 452, 459, 475 (1974). Indeed, this Court has already rejected the proposition that a licensee's ongoing payment of patent royalties negates any justiciable dispute over the validity of the patent. *Altvater* v. *Freeman*, 319 U.S. 359 (1943). Yet the Federal Circuit's insistence on compliance with its two-part test requires a patent licensee to commit a material breach of its license agreement in order to create an "actual controversy." That result is contrary to the congressional purposes behind the Act, which was adopted to free parties of the requirement that they act at their peril on their own interpretation of their rights before being able to obtain a judicial construction of those rights.

Under a proper interpretation of the Declaratory Judgment Act, this case presents an "actual contro-

versy." Petitioner claims that respondents' Cabilly II patent is invalid and not infringed. Absent respondents' patent, and their claim that petitioner's principal product infringes that patent, petitioner would not be paying royalties to respondents on its sales of that product. The dispute between the parties is concrete, specific, and susceptible of judicial resolution, and the federal courts can therefore resolve it. The fact that the litigants have entered into a license agreement, under which petitioner currently is paying royalties, is simply not significant for Article III purposes, except to the extent that petitioner's payment of royalties provides concrete proof of the extent of the parties' dispute.

The court of appeals erred in suggesting that its judgment is supported by federal patent policy. Most fundamentally, policy considerations could not justify a departure from traditional Article III principles. In any event, considerations of patent policy actually point in favor of allowing licensees in good standing to challenge the validity of patents. Many patents are clearly valid and will not be subjected to challenge by licensees. But some patents are invalid, and there is a strong federal policy, as this Court has repeatedly recognized, in ridding the economy of such patents. Licensees, moreover, are often the sole or principal parties with the requisite knowledge and incentive to challenge them. And patent owners are far from defenseless; they have been granted a valuable legal monopoly, backed by a statutory presumption of validity and the threat of powerful legal remedies. It is not inequitable to force a patent holder to defend its patent.

ARGUMENT

A PATENT LICENSEE NEED NOT BREACH ITS LICENSE AGREEMENT IN ORDER TO ESTABLISH AN "ACTUAL CONTROVERSY" UNDER ARTICLE III OR THE DECLARATORY JUDGMENT ACT

Under the interpretation of the Declaratory Judgment Act adopted by the Federal Circuit in *Gen-Probe*, *supra*, and applied below, a patent licensee in good standing cannot bring a declaratory judgment action to challenge the patent under which it is licensed. That restrictive rule has no basis in Article III, the Declaratory Judgment Act, or this Court's jurisprudence. Under settled legal principles, the fact that a licensee is in good standing does not prevent the existence of an Article III "case or controversy" between the licensee and the patent holder with respect to the validity or construction of a licensed patent. And because the "actual controversy" requirement of the Declaratory Judgment Act authorizes declaratory relief in all cases and controversies cognizable under Article III, *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 241 (1937), the Act leaves no room for the creation of heightened obstacles to justiciability that apply only in actions under the federal patent laws.

A. The "Actual Controversy" Inquiry Entails A Fact-Sensitive, Case-By-Case Examination Of The Concreteness And Reality Of The Asserted Controversy

1. This Court has made clear that the determination whether an "actual controversy" exists for purposes of the Declaratory Judgment Act necessarily entails a fact-sensitive, case-by-case inquiry. As the Court explained in *Maryland Casualty Co.* v. *Pacific Coal & Oil Co.*, 312

U.S. 270, 273 (1941), "[b]asically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

In addition, as the Court noted in *Public Service Commission* v. *Wycoff Co.*, 344 U.S. 237 (1952), "the propriety of declaratory relief in a particular case will depend upon a circumspect sense of its fitness informed by the teachings and experience concerning the functions and extent of federal judicial power." *Id.* at 243. "The disagreement must not be nebulous or contingent but must have taken on fixed and final shape so that a court can see what legal issues it is deciding, what effect its decision will have on the adversaries, and some useful purpose to be achieved in deciding them." *Id.* at 244.

2. *Wycoff* illustrates the sort of claim that this Court has consistently held does *not* present an "actual controversy." A company that transported motion picture film in Utah sought a declaratory judgment, against the state's public utility commission, that the company's business constituted "interstate commerce." 344 U.S. at 239. The Court held that the company's claim was nonjusticiable, emphasizing the abstract nature of the requested declaration: "The complainant in this case does not request an adjudication that it has a right to do, or to have, anything in particular. It does not ask a judgment that the Commission is without power to enter any specific order or take any concrete regulatory step." *Id.* at 244. Rather, the Court explained, the company sought only "to establish that, as presently conducted, [its] carriage of goods between points within as well as without Utah is all interstate commerce. One naturally

asks, so what?" *Ibid.* There was no evidence of "any past, present, or threatened action by the Utah Commission" that would affect the company's business. *Id.* at 240-241. "If there is any risk of suffering penalty, liability or prosecution, which a declaration would avoid, it is not pointed out to us." *Id.* at 245.

Similarly, in *United Public Workers* v. *Mitchell*, 330 U.S. 75 (1947), the plaintiffs sought a declaratory judgment that certain provisions of the Hatch Act were unconstitutional. *Id.* at 82-83. The Court held that the plaintiffs' general assertion of a desire to engage in prohibited political activity did not create a justiciable controversy. *Id.* at 86-91. "We can only speculate as to the kinds of political activity the [plaintiffs] desire to engage in or as to the contents of their proposed public statements or the circumstances of their publication." *Id.* at 90. Absent a more concrete dispute, "[s]uch generality of objection is really an attack on the political expediency of the Hatch Act, not the presentation of legal issues," *id.* at 89, and thus beyond the competence of the federal courts to adjudicate. See, *e.g.*, *Textron Lycoming Reciprocating Engine Div.* v. *United Auto. Workers*, 523 U.S. 653, 660-661 (1998) (no "actual controversy" over voidability of collective bargaining agreement where there was no evidence that either the union or the employer "cared about" voidability); *Golden* v. *Zwickler*, 394 U.S. 103, 109 (1969) (no "actual controversy" in declaratory challenge to state law prohibiting anonymous handbilling in elections because the Congressman targeted by plaintiff's handbills had left Congress and was unlikely to again be a candidate).

By contrast, when the parties are truly adversarial, the dispute is concrete in both its factual and legal dimensions, and the requested declaration will definitively

settle the controversy, the Court has consistently held that relief is appropriate under the Declaratory Judgment Act. In *Maryland Casualty*, for example, an insurance company sought a declaratory judgment that it was not required either to defend litigation brought against the insured by the victim of an automobile accident, or to indemnify the insured if the victim prevailed. The insurance company named both the insured and the victim as defendants. The victim moved to dismiss on the ground that no "actual controversy" existed between himself and the insurance company, and the lower courts agreed. 312 U.S. at 271-272.

This Court reversed, observing that *if* the victim prevailed in his suit against the insured and the insured did not satisfy the resulting judgment, the victim would be entitled to proceed against the insurance company by supplementary process. *Maryland Cas.*, 312 U.S. at 273. That contingent possibility, the Court explained, established an "actual controversy" sufficient to warrant declaratory relief, especially given the potential, if the victim were not a party to the federal action, for conflicting judgments in state and federal court regarding the insurance company's obligations under the policy. *Id.* at 273-274. See, *e.g.*, *Steffel*, 415 U.S. at 459; *Lake Carriers' Ass'n* v. *MacMullan*, 406 U.S. 498, 506-508 (1972); *Public Utilities Comm'n* v. *United States*, 355 U.S. 534, 538-539 (1958); *Altvater*, 319 U.S. at 363-365; *Aetna Life*, 300 U.S. at 242-244.

B. The Court Of Appeals Has Erected An Unwarranted Obstacle To Declaratory Relief In Patent Cases

Despite this Court's more nuanced approach, the Federal Circuit has adopted an inflexible two-step test for declaratory relief in patent litigation. Pet. App. 7a-

8a. Under that test, "[t]here must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Gen-Probe*, 359 F.3d at 1380 (quoting *BP Chems. Ltd.* v. *Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)); see Pet. App. 7a-8a. As the "reasonable apprehension" prong has been applied in the licensor-licensee context, moreover, the risk of litigation must be more than contingent (*e.g.*, contingent on the refusal to make the payments under the license)—the declaratory judgment plaintiff must face an actual, present apprehension of suit for an injunction, damages, or other coercive relief. See, *e.g.*, *id.* at 5a-6a. In other words, the declaratory judgment plaintiff must already have taken steps that expose it to a risk of suit.[8]

Proof that the declaratory judgment plaintiff labored under a reasonable anticipation of suit is certainly a valid means of establishing that an "actual controversy" exists. But the Federal Circuit effectively treats its two-step test as an all-encompassing restatement of the "actual controversy" requirement in the patent context, and essentially requires a breach before allowing a licensee to sue. See, *e.g.*, Pet. App. 7a-8a; *Gen-Probe*, 359 F.3d at 1379-1380. As a result, the Federal Circuit's test artificially and impermissibly limits the broad power of the federal courts to hear and decide concrete disputes be-

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[8] In at least one recent case, moreover, the court of appeals added the further gloss that an infringement suit by the patentee must be "imminent." See *Teva Pharm. USA, Inc.* v. *Pfizer, Inc.*, 395 F.3d 1324, 1334 (Fed. Cir. 2004), cert. denied, 126 S. Ct. 473 (2005).

tween adverse parties in appropriate declaratory judgment actions.

1. This Court has never suggested that a declaratory judgment plaintiff must face a present risk of suit for coercive relief before an Article III case or controversy will exist. To the contrary, the Court has specifically refused to equate "actual controversy" with the existence of an accrued cause of action for a coercive remedy. In the context of pre-enforcement challenges to criminal statutes, for example, Article III requires a declaratory judgment plaintiff to demonstrate that he faces a "genuine threat of enforcement" if he violates the proscription in question, *Steffel*, 415 U.S. at 475, and that he would be reasonably likely to engage in the proscribed conduct without the threat of enforcement, *id.* at 459. If that showing is made, however, the Constitution does not further require the plaintiff to "expose himself to actual arrest or prosecution" before a declaratory judgment will issue. *Ibid.*; see *Babbitt* v. *United Farm Workers Nat'l Union*, 442 U.S. 289, 301-302 (1979) (allowing plaintiffs to bring challenge to statutory prohibition on false or deceptive speech about agricultural products without a showing that plaintiffs had already violated the prohibition). Indeed, forcing the putative declaratory judgment plaintiff to take the step that actually exposes him to liability would frustrate the purposes of the Declaratory Judgment Act. See pp. 18-19, *infra*. Yet the court below, applying its "reasonable apprehension" test, essentially obligates patent licensees to take such a step in order to create a justiciable controversy, requiring the licensee to "materially breach[] its license," *Gen-Probe*, 359 F.3d at 1382, and thereby subject itself to the risk of an injunction and an award of

damages (potentially including treble damages and attorneys fees). See 35 U.S.C. 283, 284, 285.

There is no justification for imposing a heightened standard for justiciability in the patent context. In fact, this Court has expressly rejected the argument that a licensee's ongoing payment of patent royalties negates any justiciable dispute over the validity of the patent. In *Altvater*, *supra*, the patentees brought suit against two of their licensees to compel specific performance of the territorial restrictions in their license agreement. The licensees filed a counterclaim seeking, *inter alia*, a declaratory judgment that the underlying patents were invalid. 319 U.S. at 360-361. The licensees continued to pay royalties to the patentees "under protest," however, based both on the license agreement itself and on an injunction that the patentees had obtained in earlier litigation against the same licensees. *Id.* at 361-362. As in this case, the licensees explicitly sought to retain the right to perform under the license agreement in the event the patents were held valid and the agreement binding. See *id.* at 361. And as in this case, the patentees opposed the declaratory judgment on the ground that "so long as [the licensees] continue to pay royalties, there is only an academic, not a real controversy, between the parties." *Id.* at 364.

The Court rejected that argument and held the declaratory judgment claim justiciable, explaining that "[t]he fact that royalties were being paid did not make this a 'difference or dispute of a hypothetical or abstract character.'" *Altvater*, 319 U.S. at 364 (citation omitted). Rather, "[a] controversy was raging," and "[t]hat controversy was 'definite and concrete, touching the legal relations of parties having adverse legal interests.'" *Ibid.* To be sure, "[r]oyalties were being demanded and

royalties were being paid. But they were being paid under protest and under the compulsion of an injunction decree." *Id.* at 365. Indeed, "[i]t was to lift the heavy hand of that tribute from the business that the counterclaim was filed. Unless the injunction decree were modified, the only other course was to defy it, and to risk not only actual but treble damages in infringement suits." *Ibid.* (footnote omitted).

The court of appeals in *Gen-Probe* attempted to distinguish *Altvater* on the ground that the licensees' ongoing royalty payments in *Alvater* were not merely required by contract, but compelled by injunction. See 359 F.3d at 1381-1382. From the perspectives of Article III and the Federal Circuit's own test, there is no significance to that distinction. The licensees in *Altvater* would have failed the Federal Circuit's "reasonable apprehension of suit" test just as petitioner did. Yet the Court had little difficulty concluding that there was an "actual controversy" between the parties. That "actual controversy" flowed not from the injunction but from the dispute between the parties, "the heavy hand of * * * tribute," and the prospect of treble damages from infringement, all of which are present here.[9]

2. The court of appeals' test is inconsistent with the fundamental purposes of the Declaratory Judgment Act. It is clear that Congress did not intend the "actual controversy" requirement to obligate the declaratory judgment plaintiff to expose itself to a suit for coercive relief.

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[9] Nothing in *Altvater* indicates that the injunctive nature of the licensees' royalty obligation was dispositive. To the contrary, the Court expressly contemplated that the licensees had the option of ceasing payments and thereby risking "not only actual but treble damages in infringement suits." 319 U.S. at 365. Petitioner's options here are not meaningfully different.

To the contrary, one of the oft-stated purposes of the Declaratory Judgment Act was to enable parties to obtain a declaration of their rights in a dispute without needlessly exposing themselves to an injunction or liability for damages.

Congress recognized that, under the pre-Act state of affairs, it was "often necessary to break a contract or a lease, or act upon one's own interpretation of his rights when disputed, in order to present to the court a justifiable controversy." S. Rep. No. 1005, *supra*, at 3. The Act addressed that dilemma by "enabl[ing] disputes arising out of written instruments, or otherwise, to be adjudicated without requiring a destruction of the status quo." *Id.* at 6; see H.R. Rep. No. 1264, 73d Cong., 2d Sess. 2 (1934) ("If the meaning of a contract is controverted, for example, it may be needless to break it in order to obtain authoritative construction of the instrument, thus saving time and cost."); see also *Steffel*, 415 U.S. at 466-468 (observing that an express purpose of the Declaratory Judgment Act was to permit pre-enforcement challenges to unconstitutional state criminal statutes). The court of appeals' view that a party to a licensing agreement must breach the agreement before maintaining a declaratory judgment action in the patent context is simply irreconcilable with Congress's purposes in adopting the Act.

C. Petitioner's Declaratory Challenge To The Cabilly II Patent Presents An "Actual Controversy"

Petitioner's challenge to the validity of the Cabilly II patent and its claim of non-infringement comprise "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to

warrant the issuance of a declaratory judgment." *Maryland Cas.*, 312 U.S. at 273.

1. In this case, the parties' interests are adversarial, the factual and legal dimensions of their dispute are clear, and a declaratory judgment would conclusively resolve the issues that divide them. Petitioner is making royalty payments to respondents under a patent that petitioner claims is either invalid or not infringed by its Synagis® product (or both). Pet. App. 4a, 28a-29a. Respondents insist that the Cabilly II patent covers petitioner's sales of Synagis® and that, under the terms of the licensing agreement, petitioner must pay them royalties. *Id.* at 4a; J.A. 419-420. Although petitioner agreed, under implicit threat of suit (*ibid.*), to pay royalties after the issuance of the Cabilly II patent, it did so with the explicit warning that its payments were made "under protest and with reservation of all of our rights." J.A. 426; see J.A. 133. Furthermore, respondents do not dispute that, if petitioner had not begun paying royalties, it likely would have brought suit for infringement, breach of contract, or both.

Those facts amply demonstrate the existence of a concrete "case or controversy" under the standards enunciated by this Court for purposes of Article III and the Declaratory Judgment Act. Petitioner's contention that the Cabilly II patent is invalid and not infringed by Synagis® is wholly unlike the abstract complaints that this Court held unfit for judicial resolution in *Wycoff*, *Mitchell*, and similar cases. Indeed, respondents have not identified any respect in which this case is actually unfit for resolution by declaratory judgment, apart from the fact that there is a license agreement between the parties covering the Cabilly II patent.

2. There is no basis for concluding that the existence of a license agreement somehow transforms what would otherwise be an "actual controversy" into a non-justiciable request for an advisory opinion. For purposes of Article III and the Declaratory Judgment Act, it is simply immaterial that petitioner has entered a license agreement in order, *inter alia*, to avoid potential liability for infringement and has not breached its license agreement with respondents. What matters instead is whether there is a genuine dispute between the parties that is sufficiently concrete, specific, and substantial to warrant judicial intervention. *Maryland Cas.*, 312 U.S. at 273. If that standard is satisfied, as it is here, the fact that the parties previously agreed to enter into a licensing arrangement does not negate the existence of a controversy "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Ibid.* Indeed, when a licensing agreement involves royalty payments from a licensee that disputes the validity of the patent, the agreement is better understood as evidence of (not an obstacle to) a concrete controversy.[10]

The Federal Circuit's contrary rule, if applied consistently, would produce still further incongruous results. The requirement of a "reasonable apprehension of suit" would generally prevent non-breaching licensees from

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[10] Even if one views a license as an agreement by the *patentee* not to sue for infringement, see Pet. App. 7a; *De Forest Radio Tel. Co.* v. *United States*, 273 U.S. 236, 242 (1927), the license agreement is not a concession by the *licensee* of the validity or applicability of the patent, much less an agreement not to sue. *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969). The licensee has entered into the agreement against the inherently coercive backdrop of the presumption of validity and the powerful remedies afforded by the law to the patentee. See *Altvater*, 319 U.S. at 365.

seeking court action to resolve even those contractual disputes beyond validity and infringement. For instance, if petitioner had claimed that the license only obligated it to pay royalties at rate *A*, and respondents believed the license in fact obligated petitioner to pay royalties at higher rate *B*, that would seem to be a paradigmatic scenario for use of the declaratory judgment remedy. But, under the Federal Circuit's "reasonable apprehension of suit" test, as long as petitioner was paying respondents the higher rate *B*, even if under protest, it apparently could not bring a declaratory judgment action to settle that very real dispute.

The Federal Circuit's requirement of an open breach is antithetical to the purposes of the Declaratory Judgment Act and has no basis in any constitutional or statutory limitation on the power of federal courts. This Court's conclusion in *Altvater* applies with equal force here: Petitioner continues to pay royalties, but seeks a declaratory judgment to "lift the heavy hand of that tribute" from its business. 319 U.S. at 365. Like the licensees in *Altvater*, petitioner's only other choice is to breach the license agreement and "risk not only actual but treble damages in [an] infringement suit[]," *ibid.*, together with an injunction against the sale of a product that accounts for over 80% of its revenues. And because there is little doubt, based on respondents' immediate demand for royalties after the issuance of the Cabilly II patent, that petitioner faced a genuine risk of suit if it ceased paying royalties, all of the requirements of Article III justiciability are met. "It was the function of the

Declaratory Judgment Act to afford relief against such peril and insecurity." *Ibid.*[11]

D. The Judgment Below Cannot Be Justified By Considerations Of Patent Policy

The Federal Circuit found support for its strict interpretation of the "actual controversy" requirement in the policies of the federal patent laws. Pet. App. 7a; see *Gen-Probe*, 359 F.3d at 1382. The court stressed the "inequity" it believed would result from a rule that allowed a licensee to challenge the patent under which it is licensed, while "the patent owner, having contracted away its right to sue, is in continuing risk of attack on the patent whenever the licensee chooses—for example, if the product achieves commercial success." Pet. App. 7a. Such inequity must be avoided, the court of appeals stated in *Gen-Probe*, because it would needlessly "discourage patentees from granting licenses." 359 F.3d at 1382.

Considerations of patent policy, however, could not justify creation of a patent-specific test that is more rigorous than the constitutional and statutory standards that determine the existence of a justiciable case or controversy in all other contexts. And in any event, the applicable policy considerations (to the extent they are relevant at all) point in the opposite direction. While patent licensing in general should be encouraged be-

[11] When the licensor is the United States, however, declaratory remedies may nevertheless be unavailable for other jurisdictional reasons. For example, although a variety of federal agencies license patented technologies to the private sector, claims by licensees against the United States under such agreements would generally have to be brought pursuant to the Tucker Act, which normally does not authorize declaratory relief. See 28 U.S.C. 1491; *United States* v. *Mitchell*, 463 U.S. 206, 216 n.15 (1983).

cause it allows the efficient exploitation of technology and promotes competition and innovation, see *DOJ/FTC Licensing Guidelines* 4-6, public policy strongly favors ridding the economy of invalid patents, which impede efficient licensing, hinder competition, and undermine incentives for innovation.

1. As an initial matter, the standards governing the "actual controversy" inquiry do not vary depending on a court's assessment of the policy considerations at issue. This Court has made clear that those standards are derived from Article III itself, and that the Declaratory Judgment Act is operative "in respect to controversies which are such in the constitutional sense." *Aetna*, 300 U.S. at 240. Considerations of patent policy cannot change the constitutional analysis, and so the court of appeals' conclusion logically precludes Congress from responding based on its own assessment of patent policy. By declaring that "the *jurisdictional requirements* of a declaratory action *are not met* when royalties are fully paid to the licensor and there is no ground on which the licensor can cancel the license or sue for infringement," Pet. App. 6a (emphasis added), the court of appeals effectively placed the problem beyond the power of Congress to redress. If the court's judgment were properly grounded in Article III that consequence would be unavoidable. But Article III poses no obstacle to suits like this, and considerations of patent policy are properly evaluated by Congress, not by the courts in construing the Act's "actual controversy" requirement, which applies equally to all manner of disputes.

2. In any event, the Federal Circuit also erred in its assessment of the applicable policy considerations. The court's desire to protect patentees from the burden of defending their patents against litigation challenges

cannot be reconciled with *Altvater* (see pp. 17-18, *supra*) or *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969). To be sure, as the court of appeals recognized, *Lear* involved the substantive doctrine of "licensee estoppel," not the "actual controversy" requirement of the Declaratory Judgment Act. Pet. App. 5a-6a. But *Lear*'s holding is based on the strong federal policy favoring "full and free competition in the use of ideas which are in reality a part of the public domain," 395 U.S. at 670, a point that this Court has repeatedly underscored. See, *e.g.*, *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993) (noting the "importance to the public at large of resolving questions of patent validity"); *Blonder-Tongue Labs., Inc.* v. *University of Ill. Found.*, 402 U.S. 313, 349-350 (1971) (describing the Court's "consistent view" that "the holder of a patent should not be insulated from the assertion of defenses and thus allowed to exact royalties for the use of an idea that is not in fact patentable or that is beyond the scope of the patent monopoly granted"); *Edward Katzinger Co.* v. *Chicago Metallic Mfg. Co.*, 329 U.S. 394, 400 (1947) (noting the "necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid").

In light of those precedents, the court of appeals was wrong to suggest that it would be "inequit[able]" to permit licensees who otherwise satisfy the requirements for declaratory relief to challenge the validity of the patents under which they are licensed. Pet. App. 7a. Indeed, the Declaratory Judgment Act reflects a general judgment that it is equitable (and indeed desirable) to allow contracting parties with a dispute regarding their agreement to litigate the dispute without the necessity of an open breach. There is no basis for a special rule for pat-

ent licensees. To the contrary, when a justiciable controversy is present under the general principles of Article III, equitable considerations will normally counsel in favor of permitting such challenges in the patent context, because "[i]t is the public interest which is dominant in the patent system." *Mercoid Corp.* v. *Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944). And, as *Lear* observed, "[l]icensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery." 395 U.S. at 670.

The Federal Circuit's specific concerns about discouraging the licensing of patents and encouraging gamesmanship by licensees, see Pet. App. 7a; see also *Gen-Probe*, 359 F.3d at 1382, are overstated. Many patents are clearly valid, and thus are unlikely to be challenged. Many patent holders affirmatively desire to license their patents, and many licensees enter licensing agreements with no intent of challenging the validity of the licensed patent. Patent litigation is extremely expensive and lengthy, and often both sides will have an incentive to avoid that expense. See, *e.g.*, *Cardinal Chem.*, 508 U.S. at 99; *FTC Innovation Report*, Exec. Summary 7-8 & n.25 (noting, in 2003, that "[a] biotechnology case, for example, can cost between five and seven million dollars and take two or three years to litigate"). Moreover, there will often be other considerations, such as the existence of cross-licensing arrangements or the desire to preserve valuable business relationships, that will militate against initiation of costly and disruptive patent litigation by licensees. Indeed, the Federal Circuit's concerns are further undercut by the fact that before the creation of the Federal Circuit, case law in a number of circuits supported the notion

that licensees did not have to breach or terminate their license agreements in order to bring a declaratory action.[12]

In any event, to the extent that rejecting the *Gen-Probe* rule does encourage licensees to challenge patents through litigation, that result furthers—rather than hinders—good patent policy. As this Court has recognized, if licensees "are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification." *Lear*, 395 U.S. at 670. The Federal Circuit's rule engenders precisely that result, and thus cannot be justified on policy grounds.

3. Application of traditional "case or controversy" principles in the patent context does not leave patent owners defenseless. See *Blonder-Tongue*, 402 U.S. at 335 (noting that "patentees are heavily favored as a class of litigants by the patent statute"). The Patent Office has conferred upon the patentee a valuable property right that is "buttressed by the presumption of validity which attaches to his patent." *Lear*, 395 U.S. at 670; see 35 U.S.C. 282. Indeed, the Federal Circuit has held that "[o]vercoming the presumption requires a showing of facts proved by clear and convincing evidence." *Invitrogen Corp.* v. *Biocrest Mfg., L.P.*, 424 F.3d 1374, 1378 (Fed. Cir. 2005). This Court has thus recognized that it is not "unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue." *Lear*, 395 US. at 670.

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[12] See *Precision Shooting Equip. Co.* v. *Allen*, 646 F.2d 313, 314-319 (7th Cir.), cert. denied, 454 U.S. 964 (1981); *Warner-Jenkinson Co.* v. *Allied Chem. Corp.*, 567 F.2d 184, 187-188 & n.4 (2d Cir. 1977); *American Sterilizer Co.* v. *Sybron Corp.*, 526 F.2d 542, 545-547 (3d Cir. 1975).

In addition, a patent owner may be able to negotiate license provisions that anticipate and ameliorate the effects of the filing of a declaratory judgment action by a licensee. This Court has held that a patentee cannot require a licensee to abandon forever its right to challenge a patent, see *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224, 232-237 (1892), and that a licensee who successfully challenges a patent cannot be required to pay royalties during the pendency of the challenge, see *Lear*, 395 U.S. at 673-674. But a licensor may be able to make the filing of a declaratory judgment action a basis for terminating the license, changing the royalty rate to a specified higher rate, or otherwise adjusting the pre-challenge terms. Cf., *e.g.*, Restatement (Second) of Contracts § 356(1) (1981) ("Damages for breach by either party may be liquidated in the agreement but only at an amount that is reasonable in light of the anticipated or actual loss caused by the breach and the difficulties of proof of loss."). While the enforceability of such provisions is an open question in light of the strong public policy favoring patent challenges as reflected in *Pope* and *Lear*, those decisions do not necessarily entitle a licensee both to challenge the licensed patent and to retain all the benefits of his license agreement, if the agreement expressly provides otherwise. Cf. *Cordis Corp.* v. *Medtronic, Inc.*, 780 F.2d 991, 995 (1985) (explaining the Federal Circuit's view that *Lear* "*does* permit a licensee to cease payments due under a contract while challenging the validity of a patent. It *does not* permit the licensees to avoid facing the consequences that such an action would bring."), cert. denied, 476 U.S. 1115 (1986). In addition, a would-be licensee that makes clear that it disputes the validity or applicability of the patent may not receive the same terms as other licens-

ees. Patentees concerned about potential litigation could, for example, require prospective licensees to purchase a fully paid-up license. Therefore, the Federal Circuit's assumption that permitting suits like this will necessarily allow licensees to lock in a favorable rate and then sue may be unfounded.

4. For the foregoing reasons, the Federal Circuit's patent-policy concerns cannot justify its conclusion that declaratory actions by licensees in good standing are nonjusticiable under Article III. That is not to say, however, that district courts will be compelled to adjudicate every such dispute. As this Court has made clear, "district courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites." *Wilton* v. *Seven Falls Co.*, 515 U.S. 277, 282 (1995). Those considerations apply in patent cases just as they do in all other types of declaratory judgment actions.

Whatever the precise bounds of discretion under the Declaratory Judgment Act, however, see *Wilton*, 515 U.S. at 290, it would be inappropriate for a district court to decline to exercise jurisdiction merely on the ground that the declaratory judgment plaintiff is a licensee in good standing. To do so would be inconsistent with the reasoning of *Lear*, which is founded on the principle that the interests of federal patent law are furthered by allowing licensees to challenge the validity of patents. The *Lear* Court carefully weighed the underlying justifications for the traditional contractual doctrine of licensee estoppel against the "important public interest" in encouraging challenges to potentially invalid patents, and concluded that "the technical requirements of contract doctrine must give way before the demands of the

public interest in the typical situation involving the negotiation of a license after a patent has issued." 395 U.S. at 670-671. That determination forecloses any suggestion that vestigial notions of licensee estoppel can be employed to justify the creation of new obstacles to the adjudication of such challenges.

Beyond that, it is not necessary for the Court to determine under what circumstances a district court might decline to entertain a declaratory action by a licensee. The district court in this case had no occasion to consider that question, because *Gen-Probe* compelled it to dismiss the action. That court is in the best position to address any such discretionary matters in the first instance. See *Wilton*, 515 U.S. at 289 (vesting "district courts with discretion in the first instance, because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp").

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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MAY 2006

EXHIBIT K

No. 04-1186

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

TEVA PHARMACEUTICALS USA, INC., Plaintiff-Appellant,

v.

PFIZER, INC., Defendant-Appellee.

On Appeal from the United States Court for the District of Massachusetts
In Case No. 03-CV-10167, The Honorable Richard G. Stearns.

BRIEF OF AMICUS CURIAE FEDERAL TRADE COMMISSION SUPPORTING APPELLANT AND URGING REVERSAL

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STATEMENT OF INTEREST

The Federal Trade Commission is an independent administrative agency charged with promoting the efficient functioning of the marketplace and protecting consumer interests. Congress intended the Hatch-Waxman Act[1] to increase the flow of pharmaceuticals into the marketplace by balancing incentives for innovation by research-based pharmaceutical companies with opportunities for market entry by generic drug manufacturers. *See* H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2647-48. Consumers have benefitted from sales of lower-cost generic versions of prescription drugs. Indeed, consumers saved roughly $8-10 billion by purchasing generic equivalents of brand-name drugs in 1994 alone.[2] For any given drug, entry by more than one generic competitor typically increases the price savings.[3] The Commission therefore has an interest in ensuring that the Hatch-Waxman balance is maintained.

The Commission has developed significant expertise regarding the pharmaceutical industry and the operation of Hatch-Waxman. In 2002, the Commission completed a study of 104 drug products for which at least one

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[1] The Drug Price Competition and Patent Term Restoration Act of 1984, P.L. No. 98-417 (codified at 15 U.S.C. § 68b, 21 U.S.C. §§ 301, 355, 360cc, and 35 U.S.C. §§ 156, 271, 282).

[2] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, ix (July 1998), *available at* <ftp://ftp.cbo.gov/6xx/doc655/pharm.pdf>.

[3] *Id.* at 32.

application to market a generic drug was filed.[4] Despite the benefits that Hatch-Waxman was intended to achieve, the Generic Drug Study found that the Act contained loopholes that could be used to delay generic competition. Generic Drug Study at viii-xi, 57-58. For example, a brand-name drug manufacturer and a first generic applicant could use the Act's provisions to delay the introduction of any generic version of a drug. *Id.*

Based in part on the findings of its Generic Drug Study, the Commission testified before Congress on the operation of the Hatch-Waxman Act, including the important role that declaratory judgment actions by generic drug manufacturers play in eliminating such delays.[5] Congress adopted the Commission's two major recommendations in its recent amendments to Hatch-Waxman.[6] Commission staff have also conducted empirical economic analyses of competition in the

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[4] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* ("Generic Drug Study") (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

[5] *See, e.g.,* Letter dated October 21, 2003, from FTC Chairman Muris to Sens. Gregg and Kennedy, Senate Committee on Health, Labor, Education and Pensions, 149 Cong. Rec. S15883-03, S15886 (Nov. 25, 2003); Prepared Statement of the Federal Trade Commission Before the Committee on Judiciary, United States Senate (August 1, 2003), *available at* <http://www.ftc.gov/os/2003/08/030801pharmtest.htm.>; Prepared Statement of the Federal Trade Commission Before the Committee on Judiciary, United States Senate (June 17, 2003), *available at* <http://www.ftc.gov/os/2003/06/030617pharmtestimony.htm>.

[6] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Title XI, Access to Affordable Pharmaceuticals, PL 108-173, 117 Stat. 2066 (Dec. 8, 2003) (hereinafter, "Medicare Amendments").

pharmaceutical industry.[7] The Commission has invested considerable resources in protecting competition in the pharmaceutical industry -- it has commenced law enforcement actions against both branded and generic drug companies that have, allegedly, used certain provisions of Hatch-Waxman to impede competition.[8]

This case could play an important role in furthering competitive pharmaceutical markets and in lowering health care cost. It will create the first appellate precedent regarding whether there is a justiciable "controversy" when a subsequent generic applicant sues a patent owner or a brand-name drug manufacturer for a declaratory judgment that a listed patent is invalid or not infringed. In particular, in evaluating whether there was a controversy, the district court failed to take account of the injury that a generic drug manufacturer suffers when, as a result of actions taken by the brand-name manufacturer, it is delayed from marketing its product.

This issue has important ramifications for the operation of Hatch-Waxman because such a declaratory judgment action is, under certain circumstances, the only means by which a generic drug maker may be able to overcome the obstacle to entry created by actions of the brand-name manufacturer and the first generic applicant. If the district court's decision is upheld, it will enable first generic applicants and

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[7] *See, e.g.*, David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, Bureau of Economics Working Paper No. 248 (Feb. 2002), *available at* http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf.

[8] *See, e.g., Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order); *Abbott Labs.*, Docket No. C-3945 (May 22, 2000) (consent order); *Geneva Pharms., Inc.*, Docket No. C-3946 (May 22, 2000) (consent order).

brand-name drug manufacturers to delay substantially entry by other generic firms, and indeed by *any* generic firm (including one that has done a better job of designing around the patent), into the marketplace for a drug. This result undermines the purposes of Hatch-Waxman and will deprive consumers of the benefits of full generic competition. Thus, the Commission has an interest in this case, and respectfully submits this *amicus* brief.

STATEMENT OF THE ISSUES PRESENTED

1) Whether the district court applied the proper standard in evaluating whether there was an actual controversy between the parties.

2) Whether there is a controversy sufficient to give the court jurisdiction over Teva's declaratory judgment action.

STATEMENT OF THE CASE

A. The Hatch-Waxman Act

The Hatch-Waxman Act seeks to encourage research and development of new drugs, while speeding the introduction of generic drugs. *See* H.R. Rep. No. 98-857(I), at 14-15. The Act furthers the latter goal by permitting manufacturers seeking FDA approval to market generic drugs to submit "Abbreviated New Drug Applications" ("ANDAs") to substantially shorten the time needed to obtain marketing approval. 21 U.S.C. § 355(j); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

The Act also seeks to promote the orderly and expeditious resolution of patent disputes between brand-name drug manufacturers and generic manufacturers by

creating a patent listing and certification procedure. *See* 21 U.S.C. § 355(j). Under this mechanism, a brand-name drug manufacturer must submit to the FDA information on any patent that claims certain aspects of an approved drug and is a patent for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). The FDA's listing of such patents is known as the "Orange Book." If a generic firm (an "ANDA applicant") seeks FDA approval for a generic version of a brand-name drug before the expiration of any of the patents listed in the Orange Book, it may file a certification declaring that the patents are invalid or will not be infringed by the drug (a "Paragraph IV certification"), and notify the brand-name manufacturer of the certification. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Key provisions of Hatch-Waxman actively facilitate commencement of litigation concerning listed patents prior to generic marketing. *See* H.R. Report No. 98-857(I), at 28. First, Congress expressly provided that the filing of an ANDA containing a Paragraph IV certification constitutes an act of infringement, thus assuring that pre-marketing suits are available. 35 U.S.C. § 271(e)(2)(A); *see Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003). Second, Congress encouraged the prompt commencement of such litigation. If a brand-name manufacturer (or patent owner) sues the generic manufacturer within 45 days of receipt of a Paragraph IV certification, FDA is barred, for up to 30 months, from approving the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Otherwise FDA may grant

immediate approval. *Id.* In addition, although the statute bars the generic manufacturer from bringing a declaratory judgment action during that 45-day period, it is free to do so thereafter. 21 U.S.C. § 355(j)(5)(C).

Finally, Hatch-Waxman establishes that the first generic applicant to file an ANDA containing a Paragraph IV certification is eligible, in some situations, for 180 days of marketing exclusivity, during which the FDA may not approve subsequent ANDAs for other generic versions of the drug. 21 U.S.C. § 355(j)(5)(B)(iv). Under the 1984 version of the Act, the 180-day period begins to run as of the earlier of: (i) the first day of commercial marketing by the first generic applicant or (ii) a "decision of a court * * * holding the patent which is the subject of the [Paragraph IV certification] to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(I-II). Under the 1984 version, a court "decision" included any district court decision obtained either by the first ANDA applicant or a subsequent ANDA applicant, through declaratory judgment or otherwise, including dismissals with prejudice. *See, e.g., Minnesota Mining and Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 778, 780 (Fed. Cir. 2002); *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1008-1010 (D.C. Cir. 1999) (holding that, where a brand-name drug manufacturer (or the patent owner) covenants not to sue ANDA applicant for infringement, dismissal of ANDA applicant's declaratory judgment action for lack of subject matter jurisdiction has sufficient preclusive effect to qualify as a court "decision").

If the first ANDA applicant triggers the 180-day period and promptly brings its product to market, then it is permitted, for 180 days, to be the only generic

competitor for the name-brand drug. If, instead, a subsequent ANDA applicant triggers the 180-day period by obtaining a court decision, and the first ANDA applicant does not market its drug during that period, then the FDA may approve subsequent ANDAs, and the first ANDA applicant receives no exclusivity.

B. Hatch-Waxman Act Experience and Congressional Response

Although Congress intended Hatch-Waxman to promote competition, several of its provisions, including the 180-day exclusivity period, proved susceptible to strategies to delay generic competition. In certain instances, first ANDA applicants entered into agreements with brand-name drug manufacturers that had the effect of "parking" the 180-day period. Such agreements can delay the commencement of the 180-day period and create a bottleneck that benefits only the brand-name manufacturer and the first ANDA applicant, to the detriment of subsequent ANDA applicants and consumers. *See* FTC Generic Drug Study at vii-viii, 34, 57, 63.

Brand-name manufacturers and first ANDA applicants can create such a bottleneck if the first ANDA applicant agrees to refrain from entering the market for some period of time, and if the brand-name firm forgoes suing subsequent ANDA applicants. Such a course of conduct precludes the FDA from approving any subsequent ANDA applicants until 180 days after the first ANDA applicant enters, or until the relevant listed patents expire, or until a subsequent ANDA applicant can itself trigger the running of the 180-day period. *Id.* at vii; 57. A subsequent ANDA applicant may have a strong non-infringement defense (*e.g.*, it has done a better job of designing around the patent) capable of being decided on summary judgment and

affirmed on appeal substantially before the date the first ANDA applicant agreed to enter the market. Nevertheless, the brand-name firm and first ANDA applicant's actions still could delay that applicant from entering the market. The only way that a subsequent ANDA applicant can relieve this bottleneck would be to obtain a court decision through a declaratory judgment action.[9]

The impact of such delays is greatest when the first ANDA applicant and the brand-name manufacturer agree to a substantial delay of the date on which the first ANDA applicant enters the market. This postpones consumer access to *any* lower-priced generic version of the drug. *See* Generic Drug Study at 57, 62-63. But even a modest delay in the entry of subsequent ANDA applicants may impose substantial costs on consumers because competition among generic manufacturers has a strong impact on the price of a drug. One study found that, as the number of approved generic versions of a drug increased from one to ten, the average price for the generic version fell from 60% to 34% of the price for the brand-name version. R. Caves, *et al.*, *Patent Expiration, Entry and Competition in the U.S. Pharm. Indus.*, Brookings Papers on Economic Activity: Microeconomics, 36, table 9 (1991). For a drug like Zoloft, which had $2.7 billion in sales in 2002,[10] the cost to consumers of delaying additional generic entry would be substantial indeed.

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[9] Even if no bottleneck exists, declaratory judgment actions serve an important role because the Generic Drug Study showed that no generic applicant entered the market prior to a district court decision addressing the patents that, at the time of its application, were listed in the Orange Book. Generic Drug Study at vii.

[10] *See* Pfizer, 2002 Annual Report, *available at* <http://www.pfizer.com/are/investors_reports/annual_2002/p2002ar24_25_26_27a.htm>.

In 2003, Congress amended Hatch-Waxman (the Medicare Amendments), in large part to "close loopholes in the law * * * ." 149 Cong. Rec. S15670-03, S15745 (Nov. 24, 2003) (statement of Sen. Schumer). Among other things, one of Congress's goals was to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." *Id.*

Congress sought to eliminate this bottleneck in two ways. First, Congress strengthened the original Act's declaratory judgment provisions by explicitly directing the courts to hear declaratory judgment actions by ANDA applicants "to the maximum extent permitted by the Constitution." *Id.*; Medicare Amendments, § 1101(d)(2), amending 35 U.S.C. § 271(e) ("[T]he courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person * * * for a declaratory judgment that such patent is invalid or not infringed").

Second, Congress created a number of "forfeiture events" that cause a first ANDA applicant to lose the 180-day exclusivity. Medicare Amendments, § 1102(a)(1), amending 21 U.S.C. § 355(j)(5)(B)(iv). If a subsequent ANDA applicant resolves the patent disputes that afforded the first ANDA applicant its exclusivity -- through, for example, a court decision, a court-entered settlement that the patents are invalid or not infringed, or a withdrawal of the patents by the brand-name manufacturer -- then the first ANDA applicant must bring its generic version to market within 75 days or forfeit the exclusivity. Medicare Amendments,

§ 1101(a)(2), amending 21 U.S.C. § 355(j)(5)(C).[11] These provisions by themselves, however, do not eliminate the problem of bottlenecks unless subsequent ANDA applicants can bring declaratory judgment actions to seek court decisions of invalidity or non-infringement of listed patents.[12]

C. The Present Litigation

This case arises from the efforts of Teva Pharmaceuticals USA, Inc., to gain FDA approval to market a generic version of Pfizer's sertraline hydrochloride drug. Pfizer has marketed the drug under the trade name Zoloft since 1992 for the treatment of mood and anxiety disorders. Pfizer submitted several patents for listing in the Orange Book for the drug, including U.S. Patent No. 4,356,518 ('518 patent), which expires in December 2005, and U.S. Patent No. 5,248,699 ('699 patent), which expires in September 2010. Pfizer also holds a six-month pediatric exclusivity for the drug, extending its exclusive rights to June 2006.

In 1999, Zenith Goldline Pharmaceuticals, Inc., now known as Ivax, submitted an ANDA to market a generic sertraline hydrochloride drug. Ivax filed a "Paragraph

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[11] Congress counterbalanced these additional forfeiture events by providing that a "decision of a court" that can trigger forfeiture must be either an appellate decision or an unappealed district court decision. Medicare Amendments, § 1102(a)(2); 21 U.S.C. § 355 note. Congress, however, left unchanged the *type* of "decision" (*e.g.*, a substantive decision or dismissal with preclusive effect) that would forfeit the exclusivity. *Id.* Congress made this definition retroactive and it applies to this litigation.

[12] We take no position on the general applicability of the amendments to the present case; rather we show below that the district court erred, even assuming that the amendments are not applicable. Unless otherwise indicated, all references to the Hatch-Waxman Act are to the 1984 version.

III certification" with respect to the '518 patent (indicating that it will not enter the market until June 2006), but filed a Paragraph IV certification with respect to the '699 patent (indicating that the patent was invalid or Ivax's drug would not infringe the patent). Pfizer sued Ivax for patent infringement within 45 days, but the parties settled the dispute. Pursuant to that settlement, Pfizer granted Ivax a license under the '699 patent to manufacture generic sertraline hydrochloride commencing in June 2006 in exchange for royalty payments based on Ivax's sales.

In July 2002, Teva filed its ANDA. Teva also filed a Paragraph III certification to the '518 patent, and a Paragraph IV certification that it would market a different crystalline form of sertraline hydrochloride than the one claimed by the '699 patent or that the patent was invalid. Pfizer did not sue Teva, and also refused Teva's request for a covenant not to sue. Thus, Teva brought the present action for a declaration of non-infringement or invalidity of the '699 patent.[13] Pfizer moved to dismiss, arguing that the court lacked subject matter jurisdiction because there was no actual controversy between the parties. The court granted the motion on the basis that Teva had not demonstrated a reasonable apprehension that Pfizer would bring an infringement action against it. Accordingly, the court concluded that Teva's

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[13] Dr. Reddy's Laboratories ("DRL") also submitted an ANDA to market generic sertraline hydrochloride. Like Ivax, it did not contest the '518 patent, but contended that its marketing of a generic would not infringe the '699 patent. Pfizer took no action within 45 days and DRL sought a declaratory judgment that its marketing of the generic drug would not infringe the '699 patent. The court dismissed DRL's action for lack of jurisdiction because it was "not fully persuaded" that the declaratory judgment involved a case or controversy. *Dr. Reddy's Labs., Ltd. v. Pfizer, Inc.*, 2003 U.S. Dist. LEXIS 24351 (D.N.J. 2003).

complaint presented no case or controversy and dismissed the complaint for lack of jurisdiction.

SUMMARY OF THE ARGUMENT

Declaratory judgment actions by ANDA applicants concerning listed patents play a vital role in the Hatch-Waxman regime. These actions permit subsequent ANDA applicants to eliminate the bottlenecks that delay them from entering the market. Indeed, it would be contrary to the purpose of the Act to delay market entry by later applicants where the brand-name manufacturer and first ANDA applicant are involved in protracted litigation, or have settled their litigation without resolving the issues of validity or infringement.

The present suit involves precisely such an action. Here, the district court erred in assessing whether there was an actual controversy sufficient to create jurisdiction because it failed to consider Teva's injury (as a subsequent ANDA applicant) and Pfizer's conduct (as a brand-name manufacturer) within the context of Hatch-Waxman. Instead, it narrowly focused on whether Teva faced a reasonable apprehension of suit by Pfizer. That focus is ill-suited to evaluate an action brought by a subsequent ANDA applicant when that applicant *requires* a court decision so that it can get FDA approval to bring its product to market. If this were a "classic" non-Hatch-Waxman case, Pfizer's conduct would not create a controversy. But because of Hatch-Waxman, Pfizer's actions create a legal barrier that, absent judicial intervention, delays Teva and other subsequent ANDA applicants from marketing a product. (Part I, *infra*.)

Properly analyzed, Teva's action involves an actual controversy under Article III of the Constitution. First, Teva has a direct stake in the outcome of the litigation, which is the only means (within Teva's control) whereby it can avoid the injury it suffers from the delay in bringing its product to market. Second, that injury is traceable to Pfizer's conduct with respect to the '699 patent -- not simply in obtaining and listing that patent with the FDA, but also settling its suit with the first ANDA applicant (Ivax), failing to bring suit against Teva, and refusing Teva's request for a covenant not to sue. Third, a favorable (and prompt) decision will redress Teva's injury because if it prevails, it can gain FDA approval to market its product as soon as June 2006. (Part II.A, *infra*.)

It would be inappropriate for the district court as a matter of discretion to decline jurisdiction, because actions by subsequent ANDA applicants such as Teva directly serve Hatch-Waxman's goals. If subsequent ANDA applicants cannot bring such cases, brand-name drug manufacturers and first ANDA applicants will have the ability to "park" the 180-day exclusivity period. They could thus delay *any* generic applicant from entering the market. Finally, exercising jurisdiction over this action does not force a lawsuit on a "quiescent" patent-owner. Pfizer has engaged in a course of conduct that, under the Hatch-Waxman scheme, preserves the bottleneck that delays Teva (and any subsequent ANDA applicant) from bringing its product to market. (Part II.B, *infra*.)

This court should find that the district court has jurisdiction, not only because doing so could prevent injury to Teva, but also because consumers for sertraline

hydrochloride could benefit. Moreover, a favorable decision by this Court could also result in gains for consumers of other drugs, where competition may be limited if generic companies are unfairly blocked from entering the market.

ARGUMENT

I. THE DISTRICT COURT APPLIED AN INAPPROPRIATE TEST WHEN IT ANALYZED WHETHER TEVA'S DECLARATORY JUDGMENT ACTION INVOLVED AN ACTUAL CONTROVERSY

When the district court dismissed Teva's declaratory judgment action for lack of jurisdiction, it woodenly applied a test that is ill-suited to analyze whether a controversy exists between a subsequent ANDA applicant and a brand-name drug manufacturer concerning listed patents. In particular, the test applied by the court failed to recognize that Teva is injured by Pfizer's actions that delay it from marketing its product. As this Court has recognized, a proper analysis of whether there is an "actual controversy" that can give rise to a declaratory judgment requires careful scrutiny, in light of general principles of justiciability under Article III of the Constitution. Such an analysis must take into account the practical circumstances facing the parties, including the legal and regulatory context in which they operate, and must assess whether, under the totality of the circumstances, there is a real and immediate "controversy." *Fina Oil and Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997). Had the court below conducted such an analysis, it would have recognized that there is indeed a live controversy between Teva and Pfizer regarding the '699 patent, involving concrete injury to Teva that can be redressed by declaratory relief.

Teva seeks a remedy that, pursuant to the Declaratory Judgment Act, may be invoked by a party "[i]n a case of actual controversy" within the jurisdiction of a federal court. 28 U.S.C. § 2201(a). As this Court has explained, the "actual controversy" requirement of 28 U.S.C. § 2201(a) parallels the "case or controversy" requirement of Article III of the Constitution. *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996), *citing Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-42 (1937). To satisfy the Article III requirement, the party seeking a declaratory judgment must show: (1) that it suffered an "injury in fact" -- an invasion of a judicially cognizable interest which is "concrete and particularized," and "actual or imminent, not conjectural or hypothetical"; (2) that there is a "causal connection between the injury and the conduct complained of" -- the injury must be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court; and (3) that it is "likely," as opposed to merely speculative, "that the injury will be redressed by a favorable decision." *Bennett v. Spear*, 520 U.S. 154, 163-65, 167 (1997); *see also Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003). Because, in the declaratory judgment context, the "injury-in-fact" frequently has not yet occurred, the court must determine whether the parties have "adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Nat'l Rifle Ass'n of Am. v. Magaw*, 132 F.3d 272, 279, 280 (6th Cir. 1997) (*citing Golden v. Zwickler*, 394 U.S. 103, 108 (1969)).

To apply these requirements to patent suits, this Court frequently has employed

a "pragmatic" two-part test. *EMC Corp.*, 89 F.3d at 811-12. This test requires: "(1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999). This Court has cautioned that satisfaction of this two-part test "is not, however, a prerequisite to jurisdiction in every possible patent declaratory judgment action." *Fina Oil*, 123 F.3d at 1470. The two elements "merely assure that the declaratory plaintiff has enough interest in the subject matter of the suit and that the disagreement between the parties is real and immediate enough to fulfill the 'actual controversy' requirement." *Id.*; *see also Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14, 25-26 (1st Cir. 2001) ("a certain controversy renders the 'reasonable apprehension' question irrelevant").

The district court incorrectly analyzed whether a controversy existed between Pfizer and Teva by mechanically applying the first prong of the test, without taking into account the specific regulatory context of the Hatch-Waxman regime. This Court has stressed that "[t]here is no simple rule that addresses all shades of relationships between disputants." *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993). "'The difference between an abstract question and a "controversy" contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy.'" *Gen-Probe, Inc. v. Vysis, Inc.*, 359

F.3d 1376, 1379-80 (Fed. Cir. 2004), *quoting Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Thus, a court must resolve the issue on the "'totality of the circumstances.'" *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991), *quoting Maryland Cas. Co.*, 312 U.S. at 272. The district court failed to examine the totality of the circumstances because it ignored the impact of Hatch-Waxman on the parties.

In a "classic patent declaratory judgment suit," the ordinary two-part test is appropriate because it captures all the elements of a controversy under Article III. *Fina Oil*, 123 F.3d at 1470. Of particular relevance to this case, the first part of the test, which considers the likelihood that a patentee will actually commence an infringement suit, usually provides a good assessment of whether the plaintiff faces "injury in fact," and whether the issues have ripened sufficiently for judicial review. *See, e.g., EMC Corp.*, 89 F.3d at 811. Typically, a potential competitor is legally free to market its product in the face of an adversely-held patent. In the absence of the serious prospect of an infringement action, there is no immediate threat of legal injury, no need to invoke the power of the court and, thus, no actual controversy. *See, e.g., Cygnus Therapeutics Sys. v. ALZA Corp.*, 92 F.3d 1153, 1158-61 (Fed. Cir. 1996), *rev'd on other grounds by Nobel Pharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998); *BP Chems.*, 4 F.3d at 977-78.[14]

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[14] For example, even if the competitor faces the loss of customers or business partners who are wary of the patentee's portfolio, the competitor may resolve these harms extrajudicially -- such as by agreeing to indemnify the customers or identifying other business partners.

In contrast, in the Hatch-Waxman regime, a subsequent ANDA applicant may suffer direct legal injury and require judicial relief based not on the threat of an infringement suit, but on the ramifications of actions that a brand-name drug manufacturer has already taken concerning its patents within the regulatory scheme. As discussed above, ANDA applicants cannot legally market a drug absent FDA approval. A brand-name drug manufacturer can delay subsequent ANDA applicants from obtaining this approval if it settles its patent disputes with the first applicant, and does not sue subsequent applicants for infringement of its listed patents. This delay directly injures the subsequent ANDA applicant by depriving it of the opportunity to enter the market for the drug. The only plausible way for subsequent ANDA applicants to remedy this injury is through judicial action concerning the patents listed for the drug.

For example, under Hatch-Waxman, Teva is subject to a direct legal impediment that prevents it from marketing its product even if Pfizer does not sue to enforce its '699 patent. Teva, the subsequent ANDA applicant, has sought FDA approval to market its generic sertraline hydrochloride drug immediately after the '518 patent and the relevant pediatric exclusivity expire in June 2006. But, as a result of the entirety of Pfizer's conduct regarding the '699 patent -- including its listing in the Orange Book, its settlement of its lawsuit with the first ANDA applicant, its failure to sue Teva, and its refusal to grant Teva a covenant not to sue -- the FDA is

precluded from granting final approval to Teva.[15] In particular, the FDA may not grant approval to Teva or any other ANDA applicant (prior to the expiration of the '699 patent in 2010) until Ivax (the first applicant) has marketed its product for 180 days. 21 U.S.C. § 355(j)(5)(B)(iv)(I). Unless Teva (or another generic applicant) secures an adjudication of its dispute regarding the '699 patent, 21 U.S.C. § 355(j)(5)(B)(iv)(II), it will face a certain delay of at least 180 days before it can enter the market -- or perhaps more, if Ivax delays for any reason.[16] As noted above, the 180-day delay itself has major economic consequences for a drug such as the one at issue here. Thus, unlike the classic patent declaratory judgment suit, here Teva suffers legal injury independent of the threat of an infringement action, as a result of actions already taken by Pfizer.

The prospect of such injury, in the near future and not based on mere speculation, is fully adequate to present an actual controversy. *See, e.g. Nat'l Rifle Ass'n*, 132 F.3d at 280. Indeed, several circuit judges have explicitly suggested that an apprehension of suit may not be required to exercise jurisdiction over a declaratory judgment action by a subsequent ANDA applicant. For example, a District of Columbia Circuit panel stated that:

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[15] The Commission does not suggest that Pfizer's conduct is illegal, only that it causes injury sufficient to create an actual controversy.

[16] In *Dr. Reddy's Labs. v. Pfizer, supra,* the court treated the 180-day period as if it were Ivax's absolute entitlement, with which a subsequent ANDA filer should not interfere. *Id.* at *24-25. It is, however, not an entitlement, because, as this Court has recognized, it can be triggered as a result of a court decision brought by a subsequent ANDA applicant. *Minnesota Mining*, 289 F.3d at 780.

> It is possible that such a statutorily-created bottleneck, coupled with the statute's express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a "case or controversy" without demonstrating an immediate risk of being sued.

Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1073-74 (D.C. Cir. 1998). Similarly, Judge Gajarsa of this Court also recently opined that "the inability to market a product without a court decision may create sufficient case or controversy for the purposes of a declaratory judgment action." *Minnesota Mining*, 289 F.3d at 791 (Gajarsa, J., concurring in judgment). Thus, the two-part test applied by the district court, which focused solely on the likelihood of enforcement, did not capture the injury that Teva suffers from the bottleneck that delays it from marketing its product. That is, the district court failed to follow this Court's admonition to consider the "totality of the circumstances." *Gen-Probe*, 359 F.3d. at 1379-80. Because the district court's holding that it lacked jurisdiction was based on an inappropriate test, that decision should be reversed.

II. THE DISTRICT COURT HAS JURISDICTION OVER TEVA'S DECLARATORY JUDGMENT ACTION

A. Teva's case involves an actual controversy

Because Teva's complaint involves a real and immediate controversy, the district court had subject matter jurisdiction pursuant to Article III of the Constitution and this Court should remand the case to the district court for resolution of the merits of Teva's claims.

Teva's declaratory judgment action satisfies all the elements of an actual

controversy under Article III. As this Court has observed, these elements are "injury in fact, connection between the challenged conduct and the injury, and redressability of the injury by the requested remedy." *Allergan*, 324 F.3d at 1331. A party that has suffered "injury in fact" has been adversely affected or aggrieved and has a direct stake in the outcome of litigation. Lost opportunities to compete and lost potential future profits have been held sufficient to constitute "injuries" for the purposes of Article III. *E.g., Northeastern Fla. Chapter, Associated Gen. Contractors of America v. City of Jacksonville*, 508 U.S. 656, 664-68 (1993); *Watt v. Energy Action Educ. Found.*, 454 U.S. 151, 160-61 (1981).

Without question, Teva has a direct stake in the outcome of its case against Pfizer. If it prevails in obtaining a declaration that its generic sertraline hydrochloride drug does not infringe the '699 patent (or that the '699 patent is invalid), such a declaration will commence the running of the 180-day period and, at the end of that period, the FDA can approve Teva's ANDA. Further, if Teva gains such a decision before December 2005,[17] then Teva could then enter the market in June 2006, at the same time Ivax is scheduled to enter. Absent such a decision, Teva (and every other ANDA applicant) instead must wait for its approval until Ivax has marketed its product for 180 days, which will not occur until December 2006, at the earliest. Thus, the only way that Teva can advance the date of the approval of its product is

[17] As explained above, the decision must be one "from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken." § 1102(b)(3) of the Medicare Amendments (21 U.S.C. § 355 note).

through this litigation. Absent this action, Teva suffers an injury-in-fact from the lost opportunity to bring its product to market during the 180 days.

There is a clear connection between Pfizer's actions and Teva's injury. If Pfizer had not obtained the '699 patent and listed it in the Orange Book, settled its litigation with Ivax, declined to sue Teva, and refused Teva's request for a covenant not to sue, Teva would have had the opportunity to gain access to the market during the 180-day period. 21 U.S.C. § 355(j)(5)(B)(ii). Thus, Pfizer's actions cause Teva to suffer the financial loss from the delayed marketing of its generic sertraline hydrochloride. *See, e.g., Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-76 (1978).

Finally, a favorable decision on the merits of Teva's case will redress Teva's injury. If the Court reverses the district court's decision, it will restore Teva's opportunity to trigger the 180-day period to gain access to the market. If Teva prevails in establishing that it will not infringe the '699 patent or that the patent is invalid, then the FDA can approve Teva's ANDA. If this happens promptly, Teva will not be delayed in bringing its product to market, and it (and other ANDA applicants) will not have to forgo sales during the first 180 days after Ivax enters. *See, e.g., Watt*, 454 U.S. at 160-61; *Pac. Gas & Elec. Co. v. State Energy Res. Conservation and Dev. Comm'n*, 461 U.S. 190, 201-02, n.15 (1983).

The controversy is real and immediate, and is between adverse parties, because Pfizer's conduct creates a bottleneck that just as surely delays Teva from receiving FDA approval to market a product as if Pfizer had won a preliminary injunction in an

infringement suit against Teva. The dispute is ripe because these actions cause immediate injury to Teva greater than even an *express* threat of suit in a classic patent case.[18] Properly analyzed, and considering the reality of Teva's circumstances, Teva's complaint satisfies all elements of an actual controversy.

B. Discretionary dismissal of Teva's action is not appropriate

Although this Court has held that courts normally have discretion to decline jurisdiction over a declaratory judgment action even where there is an Article III controversy, *EMC Corp.*, 89 F.3d at 810, it would be inappropriate for a district court to do so here. Congress intended that courts take jurisdiction over declaratory judgment actions filed by subsequent ANDA applicants such as Teva.[19] Indeed, the Hatch-Waxman Act can only achieve its goals of (1) speeding access to generic drugs, *Eli Lilly & Co.*, 496 U.S. at 676, and (2) enabling early resolution of patent disputes, H.R. Report No. 98-857(I), at 28 (1984), if declaratory judgment actions are available to subsequent ANDA applicants.

Although this Court has not had occasion previously to address the issue

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[18] The analysis of whether an actual controversy exists encompasses the doctrine of ripeness. An issue is ripe if it is fit for judicial decision and if withholding consideration will cause hardship. *Cedars-Sinai Medical Center v. Watkins*, 11 F.3d 1573, 1580-81 (Fed. Cir. 1993). Here the issue is clearly fit for judicial decision because the issue before this Court is legal in nature and no further factual development is necessary. Also, withholding decision would harm Teva -- absent favorable resolution of its action, harm to Teva is certain.

[19] Indeed, when it amended the Hatch-Waxman Act, Congress specifically provided that courts should exercise jurisdiction over actions such as this one "to the extent consistent with the Constitution * * *." Medicare Amendments § 1101(d), *amending* 35 U.S.C. § 271(e).

presented here, it has generally recognized that declaratory judgment actions by a subsequent ANDA-applicant are essential to the Hatch-Waxman Act's goal of speeding access to generic drugs:

> [We agree] that § 355(j)(5)(B)(iv)(II) is triggered by the termination of an action commenced by the second ANDA filer * * * . [I]t would be contrary to the very purpose of the Act to allow the first filer to block market entry of other generic manufacturers because the first filer is involved in protracted litigation.

Minnesota Mining, 289 F.3d at 780 (internal quotation marks and citation omitted). Further, exercising jurisdiction here does not force a lawsuit on the sort of "quiescent" patentee that this Court has sought to protect. *See EMC Corp.*, 89 F.3d at 812. Pfizer brought and settled one lawsuit, thereby creating the roadblock that Teva is seeking to lift, it declined to sue Teva, and it refused to grant Teva a covenant not to sue. Absent jurisdiction over Teva's declaratory judgment action, Teva is precluded by Pfizer's conduct from entering the market as soon as it would otherwise be able, and consumers are deprived of the benefits of increased generic competition.[20] Moreover, unless there is jurisdiction in cases such as this one, subsequent ANDA applicants will be powerless to stop brand-name manufacturers and first ANDA applicants from parking the exclusivity period far beyond 180 days.[21]

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[20] Pfizer could, of course, moot the controversy by granting Teva's request for a covenant not to sue.

[21] There is nothing in the district court's decision that suggests it would have found jurisdiction if the agreement between Pfizer and Ivax had (perhaps in exchange for a payment from Pfizer to Ivax) provided that Ivax would forgo marketing its drug, for example, until 2008, 2009, or until 180 days before the '699 patent expires in 2010. If Ivax and Pfizer had done so, they could "park" the 180-day exclusivity and delay the entry of *any* generic sertraline hydrochloride drug for a matter of years.

Exercising jurisdiction over Teva's action also serves the second Hatch-Waxman goal of allowing early resolution of patent disputes. *See, e.g.*, H.R. Report No. 98-857(I), at 28 (1984) (stating that the patent certification provisions "permit[] the commencement of a legal action for patent infringement before the generic drug maker has begun marketing"). The Hatch-Waxman Act specifically contemplates actions brought by brand-name manufacturers against initial and subsequent ANDA applicants in order to resolve patent disputes before generic entry and to limit the uncertainty over potential liability that would otherwise attend generic entry. 21 U.S.C. § 355(j)(5)(B)(iii); *see, e.g.*, 130 Cong. Rec. 24427 (Sept. 6, 1984) (Statement of Rep. Waxman); *see also Warner-Lambert Co.*, 316 F.3d at 1357, 1365. Nothing in Hatch-Waxman dictates that only a brand-name drug manufacturer can initiate an action to protect its patent but that an ANDA applicant cannot protect its interests by bringing what is essentially the same action. Such a result would hinder early resolution of relevant patent disputes, where, as here, the brand-name manufacturer's interests may be served by delaying resolution of the dispute.

CONCLUSION

For the foregoing reasons the Federal Trade Commission respectfully urges this Court to reverse the district court's dismissal of the present action, and to remand the matter for resolution of the merits.

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EXHIBIT L

No. 04-1186

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

TEVA PHARMACEUTICALS USA, INC., Plaintiff-Appellant,

v.

PFIZER, INC., Defendant-Appellee.

On Appeal from the United States Court for the District of Massachusetts
In Case No. 03-CV-10167, The Honorable Richard G. Stearns.

BRIEF OF AMICUS CURIAE FEDERAL TRADE COMMISSION SUPPORTING APPELLANT'S COMBINED PETITION FOR REHEARING AND REHEARING EN BANC

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STATEMENT OF CONFLICT

The decision of the panel majority conflicts with the following decisions of the Supreme Court and this Court: *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270 (1941); *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466 (Fed. Cir. 1997); and *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731 (Fed. Cir. 1988).

STATEMENT OF INTEREST

The Federal Trade Commission is an independent federal agency that seeks to promote the efficient functioning of the marketplace and to protect consumer interests. The Commission has significant expertise in the pharmaceutical industry and the Hatch-Waxman Act. The Commission has, *inter alia*, completed a 2002 study of generic drug entry under the Hatch-Waxman Act;[1] testified before Congress on the competitive effects of the Act;[2] and commenced law enforcement actions against drug companies that have, allegedly, used portions of the Act to impede competition.[3] A declaratory judgment action, such as the one brought by Teva, could

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[1] Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* ("Generic Drug Study") (July 2002) at viii-xi, 57-58, *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

[2] *See, e.g.*, Prepared Statement of the Federal Trade Commission Before the Committee on Judiciary, United States Senate (August 1, 2003), *available at* <http://www.ftc.gov/os/2003/08/030801pharmtest.htm.>.

[3] *See, e.g., Hoechst Marion Roussel, Inc.*, FTC Dkt. No. 9293 (May 8, 2001) (consent order); *Abbott Labs.*, FTC Dkt. No. C-3945 (May 22, 2000) (consent order); *Geneva Pharms., Inc.*, FTC Dkt. No. C-3946 (May 22, 2000) (consent order).

play an important role in furthering competitive pharmaceutical markets and in lowering health care costs. Accordingly, the Commission has an interest in this case, and respectfully submits this *amicus* brief in support of Teva's combined petition for rehearing and rehearing *en banc*.[4]

STATEMENT OF THE ISSUE PRESENTED

Whether the district court applied the proper standard in evaluating whether there was an actual controversy between the parties.

STATEMENT OF THE CASE

1. The Hatch-Waxman Act seeks to encourage research and development of new drugs, while speeding the introduction of generic drugs. *See* H.R. Rep. No. 98-857(I) at 14-15 (1984). The Act attempts to speed the introduction of generic drugs by expediting the generic drug approval process, and by promoting the resolution of patent disputes between brand-name and generic drug manufacturers. The Act requires brand-name manufacturers to submit to the FDA information on certain patents that claim its drug. 21 U.S.C. § 355(b)(1). These patents are listed in what is known as the "Orange Book." A generic firm seeking FDA approval for a generic version of a brand-name drug before the expiration of such patents may certify that the patents are invalid or will not be infringed by its proposed generic (a "Paragraph IV certification"). The Act facilitates litigation concerning such patents by providing that the filing of an application for a generic drug containing a Paragraph IV

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[4] On March 31, 2004, the Commission filed a brief as *amicus curiae* in support of Teva's appeal to this Court.

certification constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2)(A).

The Hatch-Waxman Act also encourages generic manufacturers to challenge patents by providing that the first generic applicant to file an application containing a Paragraph IV certification may be eligible for a conditional 180 days of marketing exclusivity, during which the FDA may not approve subsequent generic versions of the drug. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day period begins to run as of the earlier of: (i) the first day of commercial marketing by the first generic applicant; or (ii) the date of a court decision holding that the patent at issue is invalid or will not be infringed. 21 U.S.C. § 355(j)(5)(B)(iv)(I-II). If the first generic applicant triggers the 180-day period by promptly bringing its product to market, then it is permitted, for 180 days, to be the only generic competitor for the brand-name drug. If, however, another generic firm first obtains such a court decision and the first generic applicant does not or cannot market its product during the 180 days, the exclusivity lapses and the first generic has no exclusivity. *Id.*

The 180-day exclusivity period may be susceptible to strategies to delay generic competition. In some instances, a first generic applicant could enter into an agreement with the brand-name manufacturer. The generic applicant would agree to delay entering the market, and the brand-name firm would forgo suing subsequent generic applicants. Such an agreement has the potential to delay the commencement of the 180-day period, and to preclude the FDA from approving subsequent generic applicants. Such a bottleneck would benefit only the brand-name manufacturer and the first generic applicant, to the detriment of subsequent generic applicants and

consumers. *See* Generic Drug Study at vii-viii, 34, 57, 63. The only way that a subsequent generic applicant could relieve such a bottleneck would be to obtain a court decision holding that the patent is invalid or not infringed. Such a decision would trigger the 180-day period, at the close of which the FDA may approve subsequent generics.

2. This case arises from the efforts of Teva Pharmaceuticals USA, Inc., to preclude the formation of such a bottleneck, and to gain FDA approval to market a generic version of Pfizer's sertraline hydrochloride drug, which is marketed as Zoloft. Pfizer submitted several patents to the FDA for listing in the Orange Book regarding Zoloft, including U.S. Patent No. 4,356,518 ('518 patent), which effectively expires in June 2006, and U.S. Patent No. 5,248,699 ('699 patent), which expires in September 2010. In 1999, Ivax became the first manufacturer to apply to the FDA to market generic sertraline hydrochloride. Ivax certified that it would not enter the market until June 2006, when the '518 patent expired. However, it filed a Paragraph IV certification with respect to the '699 patent (indicating that the '699 patent was invalid or would not be infringed by Ivax's drug). Pfizer sued Ivax for patent infringement and the parties settled. Pursuant to that settlement, Pfizer granted Ivax a license under the '699 patent to manufacture generic sertraline hydrochloride commencing in June 2006 in exchange for royalty payments.

In July 2002, Teva filed its application to market its generic sertraline hydrochloride. It filed a Paragraph IV certification with respect to the '699 patent indicating, just as Ivax indicated, that the '699 patent was invalid or would not be

infringed by Teva's generic. However, pursuant to Hatch-Waxman, the FDA could not approve Teva's generic until Ivax had marketed its generic for 180 days, or until 180 days after a court determination that the '699 patent was invalid or would not be infringed. But Pfizer did not sue Teva. Thus, Teva brought the present action for a declaration of non-infringement or invalidity of the '699 patent. Pfizer moved to dismiss, arguing that the court lacked subject matter jurisdiction because there was no actual controversy between the parties. The district court granted the motion on the basis that Teva had not demonstrated a reasonable apprehension that Pfizer would bring an infringement action against it, and had therefore presented no case or controversy. The panel (per Judge Schall) affirmed the district court's decision. Judge Mayer dissented.

ARGUMENT

THE PANEL MAJORITY'S ANALYSIS OF WHETHER TEVA'S DECLARATORY JUDGMENT ACTION INVOLVED AN ACTUAL CONTROVERSY CONFLICTS WITH OTHER DECISIONS OF THIS COURT

This Court has recognized that a proper analysis of whether there is an "actual controversy" that can give rise to a declaratory judgment action requires careful scrutiny, taking into account the practical circumstances facing the parties. This analysis must consider the legal and regulatory context in which the parties operate, and must assess whether, under the totality of the circumstances, there is a real and immediate "controversy." *Fina Oil and Chem. Co. v. Ewen*, 123 F.3d 1466, 1470 (Fed. Cir. 1997). Had the panel majority conducted such an analysis, it would have recognized that there is indeed a live controversy between Teva and Pfizer regarding

the '699 patent, involving concrete injury to Teva that can be redressed only by the declaratory relief it sought.

The "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), parallels the "case or controversy" requirement of Article III of the Constitution. *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996). To satisfy the Article III requirement, the party seeking a declaratory judgment must show: (1) injury in fact; (2) a causal connection between the injury and the conduct complained of; and (3) that it is likely that the injury will be redressed by a favorable decision. *Bennett v. Spear*, 520 U.S. 154, 163-65, 167 (1997). Because, in the declaratory judgment context, the "injury-in-fact" frequently has not yet occurred, the court must determine whether the parties have "adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Nat'l Rifle Ass'n of Am. v. Magaw*, 132 F.3d 272, 279, 280 (6th Cir. 1997) (*citing Golden v. Zwickler*, 394 U.S. 103, 108 (1969)).

To apply these requirements to patent suits, this Court frequently has employed what it referred to as a "pragmatic" two-part test. *EMC Corp.*, 89 F.3d at 811-12. This test requires: (1) an explicit threat by the patentee that the declaratory plaintiff will face an infringement suit; and (2) present activity that could constitute infringement. *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999). But as Judge Mayer noted in dissent, this Court has "never said that the traditional two-part test must be satisfied in every instance to find a justiciable case or controversy." Dissent at 2, *citing Arrowhead Indus. Water, Inc. v. Ecolochem,*

Inc., 846 F.2d 731, 735-36 (Fed. Cir. 1988). This Court has stressed that "[t]here is no simple rule that addresses all shades of relationships between disputants." *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993). As the Supreme Court held, "[T]he difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy." *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *see Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1379-80 (Fed. Cir. 2004).

Despite the need for flexibility when determining the existence of a case or controversy, the panel majority clearly believed that the two-part test was "a constitutional requirement." Opinion at 19. In a "classic patent declaratory judgment suit," the ordinary two-part test may well be appropriate because it captures all the elements of a controversy under Article III. *Fina Oil*, 123 F.3d at 1470. The first part of the test, which considers the likelihood that a patentee will actually commence an infringement suit, usually provides a good assessment of whether the plaintiff faces "injury in fact." *See, e.g., EMC Corp.*, 89 F.3d at 811. But in the Hatch-Waxman regime in which Teva is operating, Teva suffers direct legal injury and requires judicial relief based not on the threat of an infringement suit, but on the ramifications of actions that Pfizer has already taken concerning its patents. As discussed above, Teva cannot legally market its drug absent FDA approval, and it cannot get that approval until either: 1) Ivax has marketed its generic version for 180 days; or

2) there has been a court determination that the '699 patent is invalid or will not be infringed. As a result of Pfizer and Ivax's settlement, those two companies have complete control over the first of those two avenues. The panel majority's decision blocks the second.

The panel majority stated that the harm Teva suffers does not constitute injury in fact because it "is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme." Opinion at 24. But the panel majority ignored that Hatch-Waxman itself effectively anticipates the sort of harm at issue here, and affords parties in Teva's position an avenue by which to obtain FDA approval. In particular, Hatch-Waxman has always recognized that generic applicants like Teva may avoid the bottleneck imposed by Pfizer and Ivax's agreement if they can obtain a court determination that the '699 patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (1984).[5] By precluding Teva from even seeking such relief, the panel majority's ruling not only ignores the reality of the harm Teva suffers, but conflicts with the policies underlying Hatch-Waxman.

Teva's injury -- delay in bringing its drug to market -- will occur in the near future and is not based on mere speculation. This injury is sufficient to create an actual controversy. *See, e.g., Nat'l Rifle Ass'n*, 132 F.3d at 280. As Judge Gajarsa opined, "[t]he inability to market a product without a court decision may create

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[5] In the 2003 Medicare Modernization Act, Congress amended Hatch-Waxman and strengthened a generic applicant's ability to seek a declaratory judgment to prevent the exact harm that is occurring here. 21 U.S.C. § 355(j)(5)(C)(i)(II).

sufficient case or controversy for the purposes of a declaratory judgment action." *Minnesota Mining and Mfg. Co. v. Barr Labs. Inc.*, 289 F.3d 775, 791 (Fed. Cir. 2002) (Gajarsa, J., concurring in judgment). The test applied by the panel majority, which focused solely on the likelihood of affirmative steps by Pfizer to enforce its patent, does not capture the injury that Teva suffers.[6]

There is a clear connection between Pfizer's actions and Teva's injury. If Pfizer had not listed the '699 patent in the Orange Book and settled its litigation with Ivax, and if it had not declined to sue Teva, Teva would have had the opportunity to trigger Ivax's 180-day period of exclusivity and gain earlier access to the market. 21 U.S.C. § 355(j)(5)(B)(ii). Thus, Pfizer's actions cause Teva to suffer the financial loss from the delayed marketing of its generic sertraline hydrochloride. *See, e.g., Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-76 (1978). The controversy is real and immediate, and is between adverse parties, because Pfizer's conduct creates a bottleneck that just as surely delays Teva from receiving FDA approval to market a product as if Pfizer had won a preliminary injunction in an infringement suit against Teva. Had the panel majority properly analyzed Teva's circumstances, it would have realized that Teva's complaint satisfies all elements of

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[6] Presumably, under the panel's ruling, Teva would not be able to show "injury in fact" even if Ivax (pursuant to agreement with Pfizer or otherwise) delays its entry into the market beyond the expiration date of the '699 patent. Such a delay would be of great benefit to Pfizer because it would extend the period within which it exclusively marketed sertraline hydrochloride. Indeed, Pfizer would have no incentive whatsoever to initiate a suit against Teva because the suit might give Teva access to the market.

an actual controversy, even if it does not satisfy its ordinary two-part test.

CONCLUSION

For the foregoing reasons, the Federal Trade Commission respectfully urges that rehearing or rehearing *en banc* be granted.

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